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The National Vaccine Injury Compensation Program:

A Program Evaluation

[Redacted Version]

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Food and Drug Law/3L Paper
Professor Hutt
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Introduction

One of the greatest medical breakthroughs in history has been the advent of vaccines, which have drastically reduced the chance of naturally contracting many potentially deadly childhood illnesses. However, as the efficacy of vaccines continues to improve, their safety has become an increasing concern, as the risk of developing an adverse reaction to a vaccine may have surpassed the risk of contracting the disease.¹ Even for diphtheria-pertussis-tetanus (“DPT”) injections, which used to carry the greatest risk of adverse effects among childhood vaccinations, recipients faced a one in one hundred thousand chance of suffering permanent brain damage;² this risk is further reduced now that a safer, acellular version of the pertussis portion of the vaccine is used. “Ironically, as the safety of vaccines has increased, so has public awareness of the potential adverse side effects.”³

To address these concerns and simultaneously encourage parents to have their children vaccinated, Congress enacted the National Childhood Vaccine Injury Compensation Act (the “Act”). The Act consists of two parts: (1) the National Vaccine Program, which is concerned with improving vaccines, monitoring and tracking adverse reactions to vaccines, and supporting efforts by the Department of Health and Human Services (“HHS”) to improve immunization programs; and (2) the National Childhood Vaccine Injury Compensation Program (“NVICP”), which establishes a “no-fault” compensation program designed to efficiently and expeditiously compensate vaccine-injured children and their families.⁴ This paper primarily focuses on the NVICP as it is today and proposes recommendations to improve an innovative alternative to tort litigation.

¹ See S.A. Sturges, *Vaccine-Related Injuries: Alternatives to the Tort Compensation System*, 30 ST. LOUIS U.L.J. 919, 947 (1986).

² See Elizabeth A. Breen, *One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM. AND MARY L. REV. 309, 315 (1999).

³ *Id.*

⁴ See Lisa J. Steel, *Note: National Childhood Vaccine Injury Compensation Program: Is This the Best We Can Do for Our Children?* 63 GEO. WASH. L. REV. 144, 154 (1994).

Legislative History

Enacting this legislation was a strong indication by Congress to assume responsibility for the government's role in major products liability problems.⁵ It reflects a belief that "the class of injuries deserving compensation is broader than the class of injuries for which manufacturers of vaccines should be held responsible."⁶ However, as Calabresi ponders, why would this specific class of injured victims be chosen to receive compensation outside of the tort system, rather than others with analogous injuries?⁷ One possible explanation is that "vaccines are the only product whose use is required by law."⁸ All 50 states require children to be vaccinated before entering school,⁹ and HHS estimates that 12 million vaccinations are given to children every year.¹⁰ In addition, "approximately 56 percent of all childhood vaccine is purchased with public dollars, including federal, state and local funds; the remaining vaccine is purchased privately."¹¹

The government's role in the case of vaccines may be especially important, since relatively few children can suffer devastating injuries, and it is difficult to predict who those individuals will be ex ante. Because vaccines are given to virtually every child in the United States, even a rare adverse reaction will happen relatively frequently. "No clinical trial or FDA review could ever hope to uncover such rare events. By their very nature, they are unpredictable anyway; even if they were observed in a clinical trial, there would be no way of predicting or warning against future reactions."¹² According to one statistic, of the more than

⁵See Victor E. Schwartz and Liberty Mahshigian, *Symposium: Issues in Tort Reform: National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future?* 48 OHIO ST. L.J. 387, 398 (1987).

⁶Wendy K Mariner, *Compensation Programs for Vaccine-Related Injury Abroad: A Comparative Analysis*, 31 ST. LOUIS U.L.J. 599, 602 (1987).

⁷See Guido Calabresi, *Policy Goals of the "Swedish Alternative,"* 34 AM. J. COMP. LAW 657, 664 (1986).

⁸Susan G. Clark, *The National Childhood Vaccine Injury Compensation Program*, 94 ED. LAW. REP. 671, 674 (1994).

⁹Some children may be exempted if their parents have a religious or philosophical objection, or the vaccine is contraindicated.

¹⁰See UNITED STATES GENERAL ACCOUNTING OFFICE, REPORT TO THE CHAIRMAN, SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS, VACCINE INJURY COMPENSATION: PROGRAM CHALLENGED TO SETTLE CLAIMS QUICKLY AND EASILY 4 (1999).

¹¹NATIONAL VACCINE ADVISORY COMMITTEE, DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL VACCINE PROGRAM OFFICE, STRENGTHENING THE SUPPLY OF ROUTINELY RECOMMENDED VACCINES IN THE UNITED STATES 9 (2003).

¹²William M. Brown, *Déjà Vu All Over Again: The Exodus from Contraceptive Research and How to Reverse It*, 40 BRANDEIS L.J. 1, 43 (2001).

20 million children vaccinated per year, an estimated 500 suffer serious injuries and an additional 75 die.¹³ Because vaccine manufacturers are rational actors and “as a behavior incentive, compensating the most probable injuries encourages actors to commit resources to preventing likely injuries,” the normal deterrence methods of tort reform do not encourage these actors to “inefficiently commit resources to preventing unlikely injuries.”¹⁴

As Richard Epstein stated, “the first rule of politics is that general solutions are often very hard to achieve because there will be no sponsors to introduce them. Political action does not start with over-arching philosophical theories. It is galvanized by crisis, dramatic incidents, and by the sense of dire necessity.”¹⁵ Rather than representing “expressions of a comprehensive public policy program for disability compensation,”¹⁶ the NVICP was a product of strong public emotion, fears of vaccine shortages and ensuing epidemics of preventable diseases, and perceptions of a litigation crisis that would force vaccine manufacturers out of the market. Therefore, Congress limited NVICP to a special class of victims of a specific cause and did not purport to use this as a model for compensating victims of other injuries.

Before enacting the current structure and organizational scheme of NVICP, Congress considered other alternatives, including creating a panel under the HHS to administer a no-fault compensation program funded by private liability insurance. The panel would be authorized to enter awards up to \$1 million, or alternatively, like the NVICP, plaintiffs could reject the award and sue for tort liability, but recovery would be limited to the same amount.¹⁷

Instead, Congress chose to use the existing infrastructure within the U.S. Court of Federal Claims¹⁸ and

¹³Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD DRUG L.J. 351, 353 n.25 (2001).

¹⁴Dan L. Burk and Barbara A. Boczar, *Symposium: Biotechnology and Tort Liability: A Strategic Industry at Risk*, 55 U. PITT. L. REV. 791, 815 (1994).

¹⁵David G. Duff, *Compensation for Neurologically Impaired Infants: Medical No-Fault in Virginia*, 27 HARV. J. ON LEGIS. 391, 406 (1990).

¹⁶John G. Fleming, *Drug Injury Compensation Plans*, 30 AM. J. COMP. L. 297, 322 (1982).

¹⁷See Keith M. Garza, *Administrative No-Fault Recovery for Transfusion-Related HIV Infection*, 60 DEF. COUNS. J. 384 (1993).

¹⁸Initially, Congress considered placing jurisdiction within U.S. district courts; however the Judicial Conference of the United States and the American Bar Association raised concerns about the “case or controversy” requirement of Article III of the

passed the NVICP as part of an omnibus health care package. This decision was influenced by a number of factors. First, it was presumably unlikely that there would be a sufficient number of claims to warrant the administrative costs of creating a new independent bureaucracy.¹⁹ Second, some members of Congress and their constituencies may have been concerned with delegating authority to the HHS, who was perceived to be too heavily involved in administering the childhood immunization programs to objectively adjudicate NVICP claims.²⁰ Finally, the NVICP may have been a product of strong political opposition by the insurance companies who presumably did not want to be the sole source for the fund. Most likely a result of political compromise,²¹ Congress chose to fund the program through excise taxes paid by the vaccine manufacturers and consumers for post-1988 claims. The federal budget's general appropriations would fund pre-1988 claims awarded compensation.²²

Vaccine-related injuries are unique to other injuries since society reaps many benefits from having mandatory immunization policies. "The true issue in vaccine-related injuries is responsibility, not fault."²³ According to a Center for Disease Control ("CDC") study, "every dollar invested in vaccination reaps an estimated potential savings of eleven dollars in reduced costs of treatment."²⁴ Therefore, the excise tax²⁵ on vaccines is

Constitution, prohibiting federal courts from rendering advisory opinions, as well as concerns about the best use of judicial resources. On the other hand, Article I courts, like the Court of Federal Claims, has jurisdiction nationwide, specific authority to appoint special masters, and is not bound by the Seventh Amendment to hold jury trials in suits brought against the United States. See MOLLY TREADWAY JOHNSON, ET AL., FEDERAL JUDICIAL CENTER, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 9 (1998).

¹⁹See MANITOBA LAW REFORM COMMISSION, COMPENSATION OF VACCINE-DAMAGED CHILDREN 37 (2000).

²⁰See MOLLY TREADWAY JOHNSON, ET AL., FEDERAL JUDICIAL CENTER, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 9 (1998).

²¹Although President Reagan opposed the program based on separation of powers grounds since the judiciary, rather than the executive, was charged with its administration, he signed the package, in part due to the lack of funding which rendered the program at least temporarily ineffective. However, Congress bypassed a potential presidential veto by funding the NVICP through an amendment to the Omnibus Budget Reconciliation Act of 1987, and the NVICP became a reality. See Keith M. Garza, *Administrative No-Fault Recovery for Transfusion-Related HIV Infection*, 60 DEF. COUNS. J. 384 (1993).

²²NVICP went into effect on October 1, 1988, and the Act made special provisions for pre-1988 claims. See MANITOBA LAW REFORM COMMISSION, COMPENSATION OF VACCINE-DAMAGED CHILDREN 26 (2000).

²³S.A. Sturges, *Vaccine-Related Injuries: Alternatives to the Tort Compensation System*, 30 ST. LOUIS U.L.J. 919, 934 (1986), citing McIntosh, *Liability and Compensation Aspects of Immunization Injury: A Call for Reform*, 18 OSGOOD HALL L.J. 584, 609 (1980).

²⁴Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 288 (Mar. 1985), citing Hinmon & Koplan, *Pertussis and Pertussis Vaccine; Reanalysis of Benefits, Risks, and Costs*, 251 JAMA 3104, 3109 (1984).

²⁵For injuries before October 1, 1988, the effective date of the Act, compensation is from appropriated funds. For pre-Act cases through 1992, Congress appropriated \$80 million per year and \$110 million per year after 1992 until no further compensation is

an appropriate method of funding the compensation fund, since “the parties receiving direct personal benefit from being vaccinated are bearing the cost of compensating those injured by adverse reactions.”²⁶ Using the excise tax establishes a link between those benefiting from the vaccines and those injured by them.

However, like tort law, “there is no necessary financial link between those who cause injury and those who suffer injury; rather, costs are either borne or redistributed according to the social goal to be accomplished.”²⁷

Even if costs were directly borne by the manufacturers, manufacturers often “pass through” some of these higher costs to consumers in the form of higher prices. However, one statistic suggests that manufacturers might still bear most of the costs. According to one author, “two-thirds of all companies with at least \$100 million in sales charge one percent or less for insurance in their final prices, and for another eleven percent, liability insurance accounts for only two to three percent of the final price.”²⁸ However, the true cost might fall on developing innovative technologies with uncertain attributes, where the perception of high liability may deter manufacturers from developing more effective vaccines or from entering the market at all, where presumably more manufacturers would enhance competition and improve the overall quality of vaccines.

In comparison to other highly profitable prescription drugs, vaccines are relatively unprofitable, since most vaccines only require one inoculation in a lifetime. If that one dose exposes the manufacturer to enormous tort liability, the profit per dose may be comparatively low and the perceived liability exponentially high.²⁹

One statistic estimates that in 1982, “the estimated cost for developing and marketing a single new vaccine was between twenty and fifty million dollars, while the industry’s total annual vaccine sales were only \$172

required for pre-Act cases. See MOLLY TREADWAY JOHNSON, ET AL., FEDERAL JUDICIAL CENTER, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 11 (1998).

²⁶H. William Smith III, *Note: Vaccinating AIDS Vaccine Manufacturers Against Product Liability*, 42 CASE W. RES. 207, 251 (1992).

²⁷Dan L. Burk and Barbara A. Boczar, *Symposium: Biotechnology and Tort Liability: A Strategic Industry at Risk*, 55 U. PITT. L. REV. 791, 807 (1994).

²⁸John P. Wilson. *The Resolution of Legal Impediments to the Manufacture and Administration of an AIDS Vaccine*, 34 SANTA CLARA L. REV. 495, 514 (1994).

²⁹See Kelley E. Cash, *The New Restatement (Third) of Torts: Is it the Cure for the AIDS Vaccine Ailment?* 16 REV. LITIG. 413 (1997).

million.”³⁰ However, one commentator doubts that the vaccine market is unprofitable, arguing that the small number of manufacturers in the market represents a virtual oligopoly and those manufacturers are assured of a stable market since all states require immunization before school enrollment.³¹

In addition to the manufacturers’ fears of liability, insurers began denying the availability of products liability insurance or increasing their premiums, as “insurance companies are no more eager to lose their shirts to unpredictably generous juries than are the vaccine manufacturers themselves.”³² As a result, the only manufacturers left in the market markedly increased their prices, making it more difficult to maintain high rates of vaccination.³³ For example, the cost per dose of the DPT vaccine increased forty cents from 1982 (\$11) to 1986 (\$11.40), with eight dollars of this price going to liability insurance.³⁴ When liability insurance costs for vaccine manufacturers were rapidly growing between 1980 and 1986, prices for some vaccines rose by over 300 percent.³⁵

Some argue that vaccine manufacturers’ perception of their liability risk in the 1980’s was justified; others argue that it was simply a perception. According to one scholar, vaccines accounted for five to fifteen percent of a pharmaceutical company’s total sales, yet constituted forty percent of its liability claims and sixty percent of its total insurance costs.³⁶ Between 1980 and 1984, vaccine injury victims demanded \$3.5

³⁰Paula M. Simpkins, *Rejection of Market-Share Liability for Childhood Vaccine Manufacturers: Shackil v. Lederle Laboratories*, 43 RUTGERS L. REV. 819, 836 (1991).

³¹*Id.*

³²Richard C. Ausness, *Unavoidably Unsafe Products and Strict Products Liability: What Liability Rule Should be Applied to the Sellers of Pharmaceutical Products?* 78 KY. J.L. 705, 752 (1990), quoting Peter Huber, *Safely and Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 287 (1985).

³³MOLLY TREADWAY JOHNSON, ET AL., FEDERAL JUDICIAL CENTER, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 8 (1998).

³⁴See Gregory C. Jackson, *Pharmaceutical Product Liability May be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U.L. REV. 199 (1992), citing Gina Kolata, *Litigation Causes Huge Price Increases in Childhood Vaccines*, 232 SCIENCE 1339, 1339 (1986).

³⁵MOLLY TREADWAY JOHNSON, ET AL., FEDERAL JUDICIAL CENTER, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 8 (1998).

³⁶See S.A. Sturges, *Vaccine-Related Injuries: Alternatives to the Tort Compensation System*, 30 ST. LOUIS U.L.J. 919, 920 (1986), citing DIVISION OF HEALTH PROMOTION AND DISEASE PREVENTION, INSTITUTE OF MEDICINE, VACCINE SUPPLY AND

billion in damages, inducing six manufacturers to leave the vaccine market and leaving only two behind.³⁷ Vaccine manufacturers spent an estimated \$4.7 million and \$9.8 million, respectively for 1983 and 1984, in litigation costs defending against tort claims resulting from adverse reactions to vaccines.³⁸ However, manufacturers' net vaccine sales during 1983 and 1984 were \$156.9 million and \$190.5 million, respectively, paying only three to five percent of their net sales revenues for litigation expenses.³⁹ Regardless of whether the pharmaceutical companies' liability fears were well-founded, their perceptions of liability induced them to exit the vaccine market. "In the period between 1968 and 1977, the number of licensed vaccine manufacturers in the United States decreased by approximately fifty percent. Within the same period, the number of licensed vaccine products decreased by sixty percent."⁴⁰ Without additional information such as the amount spent on research and development and the cost of producing the vaccine once it was developed, "the conclusion that vaccine manufacturers [were] unduly burdened by tort liability seems premature."⁴¹

"Whether . . . problems with liability insurance arise from a crisis in the tort system or from a bad downturn in the business cycle of the insurance industry has been and remains a matter of great controversy."⁴² Nevertheless, regardless of the accuracy of their fears of liability, vaccine manufacturers (along with frustrated parents of injured children seeking relief from litigating their claims in court) succeeded in helping to pass

INNOVATION 53 (1985).

³⁷ See Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U.L. REV. 1853, 1856-57 (1995).

³⁸ See H. William Smith III, *Note: Vaccinating AIDS Vaccine Manufacturers Against Product Liability*, 42 CASE W. RES. 207, 234 n.177 (1992).

³⁹ See Paula M. Simpkins, *Rejection of Market-Share Liability for Childhood Vaccine Manufacturers: Shackil v. Lederle Laboratories*, 43 RUTGERS L. REV. 819, 836 (1991).

⁴⁰ S.A. Sturges, *Vaccine-Related Injuries: Alternatives to the Tort Compensation System*, 30 ST. LOUIS U.L.J. 919, 935 (1986), *citing* OFFICE OF TECHNOLOGICAL ASSESSMENT REPORT: A REVIEW OF SELECTED FEDERAL VACCINE AND IMMUNIZATION POLICIES 5 (1979). In 1986, there was one manufacturer of the polio vaccine, one of the measles, mumps and rubella vaccine, and two of the diphtheria, pertussis, and tetanus vaccine. MOLLY TREADWAY JOHNSON, ET AL., FEDERAL JUDICIAL CENTER, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 8 (1998).

⁴¹ Paula M. Simpkins, *Rejection of Market-Share Liability for Childhood Vaccine Manufacturers: Shackil v. Lederle Laboratories*, 43 RUTGERS L. REV. 819, 854 (1991).

⁴² *Id.* at 856, *quoting* The Committee on Energy and Commerce in H.R. REP. No. 908, 99th Cong., 2d Sess. 6, *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 6344, 6347.

NVICP. A representative from one pharmaceutical company testified at the Congressional hearings leading up to the Act that his company, “among others, made a major financial contribution to support the IOM [Institute of Medicine, National Academy of Sciences] study,”’ which subsequently recommended a no-fault compensation system for vaccine-related injuries.⁴³

NVICP as a Model For Tort Reform?

⁴³Kristine M. Severyn. *Jacobson v. Massachusetts: Impact on Informed Consent and Vaccine Policy*, 5 J. PHARMACY & LAW 249, 262 (1995).

Tort reform has long been debated, especially in areas where complex and technical issues of causation are at stake. As one commentator notes,

The American level of awards for non-pecuniary loss, the contingent fee, the vagaries of trial by jury, the relatively liberal availability of punitive damages, and community hostility toward centralized state control of substitute schemes that would keep the administration costs down, suggest that reform efforts based on the offering of substitutes will never succeed. Yet, the American tort system appears to be an expensive, incoherent mess about which little positive can be said. Society would be better off without it.⁴⁴

Because of the many shortcomings of the tort system, including protracted and expensive trials, the unpredictability of jury verdicts and damages awards, inefficient allocations of resources,⁴⁵ and overdeterrence, provoking many pharmaceutical companies to leave the area of vaccine research and development, the NVICP has become a model for many areas of tort reform.

Compensating victims of vaccine-related injuries and shielding vaccine manufacturers from liability in order to ensure a steady supply of childhood vaccines were the main motivations for Congress to pass the NVICP. The tort process had become too much of a “lottery” where a small number of people received a windfall of compensation, while the vast majority went uncompensated. Instead of focusing on any misconduct by pharmaceutical companies, the program focuses on compensating victims for injuries from participating in a program that yields tremendous societal benefits. “[A] shift from the emphasis on corrective justice that is the hallmark of tort law toward forced insurance—a characteristic goal of cause-based programs—has been decisively made.”⁴⁶

This “collective liability”⁴⁷ approach is particularly appropriate in national vaccination programs, where courts in traditional tort litigation are not accustomed to regulating public risks and making progressive

⁴⁴Sir Geoffrey Palmer, *The Ninth Monsanto Lecture: The Design of Compensation Systems: Tort Principles Rule, O.K.?* 29

choices based on cost-benefit analysis. This comparative risk regulation is outside the courts' usual venue of private risks "amenable to rational control through the retail, retrospective regulation that courts have traditionally applied."⁴⁸ Public agencies may be better positioned and competent to overcome the congressional and judicial bias towards specific and visible victims, and appropriately balance the risks of harm from approved drugs with the risk of the consequences of delay in marketing new drugs or failing to develop them at all that produces unknown and unidentifiable victims.⁴⁹ "The 'go slow' judicial philosophy is not a choice between safety and risk. It is a choice in favor of old risks and against new ones. Though they may prefer to believe otherwise, the courts are incapable of saying only 'no' to risk; the rejection of one risk is always the acceptance of another."⁵⁰

The NVICP serves as a particularly effective model for compensation through insurance, rather than tort litigation, for "diseases which are well understood and for which adverse reactions to vaccines are highly predictable."⁵¹

Administrative compensation schemes offer greatest promise when the compensation-triggering "event" features a relatively clear relationship between source, substance, and pathological condition. . . . In such cases, no-fault has the dual advantage of providing an insurance principle for awarding compensation and assigning losses commensurate with more optimal deterrence. When one ventures, however, into the unconfined area of mass toxic harms, administrative compensation schemes share many of the burdens that beset a reconstructed aggregative tort liability approach.⁵²

Compensation for Illness and Injury, 93 Colum. L. Rev. 75, 94-95 (1993).

⁴⁷ See Gregory C. Jackson, *Pharmaceutical Product Liability May be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U.L. REV. 199 (1992).

⁴⁸ Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 331 (1985)

⁴⁹ *Id.* at 308 n.113, citing Seidman, *Protection or Overprotection in Drug Regulation?* THE POL. OF POL'Y ANALYSIS, REG. 22, 35 (1997).

⁵⁰ *Id.* at 308-309.

⁵¹ H. William Smith III, *Note: Vaccinating AIDS Vaccine Manufacturers Against Product Liability*, 42 CASE W. RES. 207, 240 (1992).

For diseases with unknown side effects, the causation question—the only issue for the adjudicators to determine before compensating victims—becomes highly controversial and the proceedings become a “microcosm” of the very tort system it aspired to replace.

Difficulties in Proving Causation

Even with the NVCIP, the “compensable event” is difficult to determine at times. “It is a thorny issue for medical accidents generally in that the definition of a compensable event seems sufficiently similar to the fault standard in tort to reproduce the uncertainties and attendant administrative costs of that system thus negating much of the advantage of no-fault.”⁵³ The Vaccine Injury Table (the “Table”) is designed to facilitate this problem by specifying known adverse reactions associated with specific vaccines within a given time period.⁵⁴ If the plaintiff can show that his/her injury is one recognized under the Table, then the presumption of causation is in his/her favor, shifting the burden of proof to the government to show that the injury was caused by a specific factor unrelated to the vaccine. If the plaintiff’s injury is not within the Table’s definitions, then he/she has to prove by a preponderance of the evidence that the vaccine indeed caused the injury without any presumption of causation in his/her favor.⁵⁵

The actual implementation of the Table and the corresponding presumption may become as difficult to prove as causation is in tort litigation. In *Shalala v. Whitecotton*,⁵⁶ the Supreme Court held that “a demonstration that the claimant experienced symptoms of an injury during the Table period, while necessary, is insufficient to make out a prima facie case. The claimant must also show that no evidence of the injury appeared before

⁵³Craig Brown, *Hepatitis C: Eight Questions About No-fault Compensation for Blood-Product Harm*, 18 WINDSOR Y.B. ACCESS JUST. 217, 221 (2000).

⁵⁴The Vaccine Injury Table and the Secretary’s Qualifications and Aids to Interpretation can be found, *infra* Appendix D.

⁵⁵See Lisa J. Steel, *Note: National Childhood Vaccine Injury Compensation Program: Is This the Best We Can Do for Our Children?* 63 GEO. WASH. L. REV. 144, 156-157 (1994).

⁵⁶514 U.S. 268, 115 S.Ct. 1477 (1995).

the vaccination.”⁵⁷ In addition, even if a victim falls a few hours outside the time period specified in the Table, special masters are justified in denying recovery. Although special masters have incredible discretion in almost every other aspect of the proceeding and evidentiary standards, they generally strictly adhere to the Table requirements. “The probability that a fact exists in the petitioner’s favor is not sufficient to establish it as true. Rather, the special master ‘must believe that the existence of a fact is more probable than its nonexistence, before the [special master] may find in favor of the party who has the burden to persuade.”⁵⁸

In addition, the Table has not been significantly modified to reflect new scientific evidence since the Act’s implementation. The Table was “derived based on epidemiological studies of adverse reactions to the covered vaccines and reports of the American Medical Association and the American Academy of Pediatrics.”⁵⁹ The Secretary of Health and Human Services (the “Secretary”) has the authority to amend the Table as deemed necessary, usually based on the research and findings of the Institute of Medicine (“IOM”), a division of the National Academy of Science, and the Advisory Commission on Childhood Vaccines (“ACCV”).⁶⁰ The Secretary has recently added Hepatitis B, conjugated and unconjugated *Haemophilus influenza* B (Hib), varicella (chicken pox), rotavirus, and pneumococcal vaccines to the Table.⁶¹

With the exception of adding these vaccines to the program, the Secretary has sought to narrow the injuries

⁵⁷*Id.* at 269, 115 S.Ct. at 1478 (1995).

⁵⁸Elizabeth A. Breen, *One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM AND MARY L. REV. 309, 325 (1999).

⁵⁹MOLLY TREADWAY JOHNSON, ET AL., FEDERAL JUDICIAL CENTER, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 13 (1998).

⁶⁰*See* 42 U.S.C.A. §300aa-19(f)(2).

⁶¹On August 6, 1997, hepatitis B, *Haemophilus influenza* type b, and varicella (chicken pox) vaccines were added to the VICP. On October 22, 1998, rotavirus vaccine was added. And on May 22, 2001, pneumococcal conjugate vaccines were added. *See* Health Resources and Services Administration, Office of Special Programs, *National Vaccine Injury Compensation Program*, at <http://www.hrsa.gov/osp/vicp/dvicprog.htm>.

covered under the Table and deny plaintiffs the presumption of causation rather than using her powers to expand the Table and therefore, coverage under the program. In 1995 and 1997, the Secretary removed more general and common disorders such as residual seizure disorder and shock collapse and restricted the definition of encephalopathy. In their place, the Secretary added rarer and more specific adverse reactions, such as chronic arthritis, brachial neuritis, and thrombocytopenic purpura. About 44.7 percent of the claims compensated through February 1999 were associated with Table injuries the Secretary removed in 1995 and 1997.⁶² As a result, removing some of the more common vaccine-related injuries from the Table makes it more difficult to prove causation and receive compensation.⁶³ Most of the plaintiffs who file claims and receive compensation allege Table injuries. As of February 1999, about 28 percent of plaintiffs filed non-table injury claims and therefore, had the burden of proof to show that the vaccine indeed caused their injuries. Of these, only 13 percent received compensation, while 35 percent of those who filed Table injury claims received compensation.⁶⁴

The Table changes were partly based on the IOM's studies conducted in 1991 and 1994 that concluded that there was insufficient evidence to support the absence or presence of a causal relationship between vaccines and those conditions the Secretary ultimately removed.⁶⁵ However, the Secretary only removed a few of those that the IOM concluded there was "insufficient medical evidence to prove or disprove a relationship," since IOM found this to be true for two-thirds of the 75 medical conditions studied.⁶⁶ HHS stated that it also considered the level of risk of compensating an excessive number of non-vaccine-related

⁶²See UNITED STATES GENERAL ACCOUNTING OFFICE, REPORT TO THE CHAIRMAN, SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS, VACCINE INJURY COMPENSATION: PROGRAM CHALLENGED TO SETTLE CLAIMS QUICKLY AND EASILY 12 (1999).

⁶³See Jaclyn Shoshana Levine, *The National Vaccine Injury Compensation Program: Can It Still Protect an Essential Technology?* 4 B.U. J. SCI. & TECH. L. 9, *51 n.118 (1997).

⁶⁴See UNITED STATES GENERAL ACCOUNTING OFFICE, REPORT TO THE CHAIRMAN, SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS, VACCINE INJURY COMPENSATION: PROGRAM CHALLENGED TO SETTLE CLAIMS QUICKLY AND EASILY 12 (1999).

⁶⁵See *id.* at 13.

⁶⁶*Id.* n.13.

injuries for the extremely rare vaccine-related case.⁶⁷ Unfortunately, HHS has interpreted the Act’s legislative history as recognizing Table injuries only when definitive medical evidence establishing causation is available, while others interpret Congress’s intent as including injuries in the Table until definitive medical evidence excludes them, giving the petitioner the benefit of the doubt when causation is questionable.⁶⁸ According to the General Accounting Office (“GAO”), “HHS based its decisions to add or remove Table injuries on various factors but did not have a clear and transparent methodology to demonstrate that these factors were consistently applied for each injury Table change. Without such transparency, changes that make compensation more difficult for petitioners may continue to be questioned by some, regardless of their merit.”⁶⁹

One commentator has suggested that like adding vaccines to the Table, any changes made to the Table should be subject to congressional review. For Table changes, the Secretary is only required to provide a 180-day public notice and comment period and a 90-day review period by the ACCV. “Because potential table changes require balancing existing knowledge of causation against the spirit of the NCVIA, Congress should be in the position to make these weighty policy determinations,”⁷⁰ rather than having the Secretary unilaterally make decisions currently dominated by uncertain scientific causation evidence.

Long Adjudications

The program has also been criticized for taking too long to adjudicate claims. The Act requires that special masters render a judgment within 240 days of filing, exclusive of suspended time. If a special master fails to

⁶⁷ See *id.* at 15.

⁶⁸ See *id.*

⁶⁹ See *id.* at 3.

⁷⁰ Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD DRUG L.J. 351, 364 (2001).

do so or if appealed and judgment is not rendered within 420 days, petitioner has the right to withdraw the claim and sue the vaccine manufacturer or health care provider directly in civil court for tort remedies.⁷¹ Despite the statute's clear time limits on when decisions should be rendered after petitioner files the claim, special masters often grant delays requested by Department of Justice ("DOJ") attorneys deemed reasonable by the special masters.⁷² In a 1999 study by the GAO, only 14 percent of claims were processed in one year or less; most took at least two years. This may be partly attributed to the large influx of pre-1988 cases that were filed before the January 31, 1991 deadline to file such cases.⁷³ 3,263 and 980 claims were filed in 1990 and 1991, respectively, compared to 75 and 125 filed in 1988 and 1989, respectively.⁷⁴ In 1988 and 1989, nearly all of the approximately 200 claims filed were processed within two years. In comparison, more than 1,000 cases were still pending by the end of 1995. The GAO's data is shown below in Figures 1 and 2.⁷⁵

[REDACTED]

[REDACTED]

The long delays may also be attributed to the fact that in 1990, the DOJ and HHS received additional funding for staff and expert witnesses to defend vaccine claims and therefore, had increased resources to challenge more claims where causation was in doubt. After a petitioner files a claim with the U.S. Court of Federal Claims, the claim is forwarded to the Public Health Service ("PHS"), whose medical experts in the Division of Vaccine Injury Compensation ("DVIC") make their initial determination and recommendations of whether the claim should be compensated under the Act. The PHS Office of General Counsel reviews its opinion and forwards it to the DOJ.⁷⁶ The PHS has 90 days to submit their report to the Court of Federal

⁷¹ See 42 U.S.C.A. § 300aa-21(b).

⁷² See, e.g., 42 U.S.C.A. §300aa-12(d)(3)(C).

⁷³ See UNITED STATES GENERAL ACCOUNTING OFFICE, REPORT TO THE CHAIRMAN, SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS, VACCINE INJURY COMPENSATION: PROGRAM CHALLENGED TO SETTLE CLAIMS QUICKLY AND EASILY 9 (1999).

⁷⁴ *Id.*

⁷⁵ *Id.* at 8, 10.

⁷⁶ See OFFICE OF INSPECTOR GENERAL, THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM: A PROGRAM REVIEW

Claims.

Delays can occur at any point along this system, as well as in the production of medical records and other necessary documents, the entitlement proceeding, and the damages proceeding. First, HHS data show that the DOJ attorneys often requested supplemental medical records or other information from plaintiffs, most of whom took at least a year to comply. Second, whenever the PHS physician decides that a case is not compensable, the case is sent to an outside medical expert, who may request additional information to form an opinion in the case, which then becomes the official PHS decision, referred to as the “internal report.”⁷⁷ Finally, expert witnesses from both sides then take time to review the records, and special masters sometimes take another year to reach their decisions.⁷⁸

(1992).

⁷⁷ See *id.* at Appendix A.

⁷⁸ See *id.* at 11.

Limits on Tort Recovery Under the Act

The program is designed to discourage tort litigation for more certain and quicker, albeit potentially less generous, compensation from the federal government.⁷⁹ The goal of reducing tort litigation against manufacturers seems to have been achieved. In 1986, more than 250 lawsuits were filed against DPT manufacturers; by 1997, petitioners filed only four lawsuits.⁸⁰ In addition, Congress hoped that a relatively uniform federal standard for compensating vaccine victims would give similarly situated individuals comparable compensation, rather than subjecting victims to different state tort laws.⁸¹

Some believe that to achieve optimal predictability for vaccine manufacturers with respect to their liability and uniformity in compensation awards for injured plaintiffs, the Act should make its compensation scheme the exclusive remedy. One commentator believes that although this may invoke some to challenge the constitutionality of the statute on due process grounds, “the U.S. Supreme Court has consistently held that plaintiffs have no vested right to tort claims under state law.”⁸² However, preserving the plaintiffs’ right to sue for tort damages was most likely more politically palatable and therefore, feasible. The non-exclusiveness of the program’s remedy is not unique to a litigious American society; most countries that have compensation programs allow claimants to institute a civil action for damages in addition to, or instead of, the compensation program.⁸³

⁷⁹See John P. Wilson, *The Resolution of Legal Impediments to the Manufacture and Administration of an AIDS Vaccine*, 34 SANTA CLARA L. REV. 495, 553 (1994).

⁸⁰See Elizabeth A. Breen, *One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM. AND MARY L. REV. 309, 319 n.84 (1999).

⁸¹See Mary Beth Neraas, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?* 63 WASH. L. REV. 149, 162-163 (1988).

⁸²Keith M. Garza, *Administrative No-Fault Recovery for Transfusion-Related HIV Infection*, 60 DEF. COUNS. J. 384, 389 (1993).

⁸³These countries include Denmark, France, Germany, Italy, Japan, Norway, Quebec, Switzerland, Taiwan and United Kingdom. See Wendy K Mariner, *Compensation Programs for Vaccine-related Injury Abroad: A Comparative Analysis*, 31 ST.

Although the Act allows plaintiffs to sue the vaccine manufacturers for tort liability, the Act makes subsequently filing a successful tort claim much more difficult. It requires plaintiffs to first exhaust their administrative remedies by filing a claim under the Act. If their claim is denied or they are unsatisfied with the level of compensation, only then may they sue the pharmaceutical company in civil court under restricted theories of liability. First, the Act prevents plaintiffs from suing under strict liability, protecting vaccine manufacturers through the Restatement (Second) of Torts section 402A comment k's "unavoidably unsafe" doctrine.⁸⁴ Second, pharmaceuticals are shielded from any claim that they breached their duty to warn patients by employing the learned intermediary doctrine, allowing them to fulfill their duty by warning the treating physician only.⁸⁵ Finally, pharmaceutical companies that comply with Food and Drug Administration ("FDA") regulations on warnings enjoy a presumption that these warnings are indeed adequate.⁸⁶ Unless the manufacturer intentionally withheld material information from the FDA or otherwise committed fraud, no punitive damages will be awarded.⁸⁷

Some critics argue that these liability shields have decreased vaccine manufacturers' incentives to invest in research and development of safer vaccines. Once declared as "unavoidably unsafe," it implies that there is nothing further in the vaccine's design to make it any safer. "By insulating vaccine manufacturers from strict design defect liability, the Vaccine Act implicitly announces that the Federal Government is satisfied with the current state of vaccine safety, and that the Government will not use the tort system to encourage

LOUIS U.L.J. 599, 612 (1987); Geoffrey Evans, *Vaccine Injury Compensation Programs Worldwide*, VACCINE 17 S25, S26 (1999).

⁸⁴ See 42 U.S.C.A. § 300aa-22(b)(1).

⁸⁵ See 42 U.S.C.A. § 300aa-22(c).

⁸⁶ See 42 U.S.C.A. § 300aa-22(b)(2). See also Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U.L. REV. 1853, 1856-57 (1995).

⁸⁷ See William M. Brown, *Déjà Vu All Over Again: The Exodus from Contraceptive Research and How to Reverse It*, 40 BRANDEIS L.J. 1, 45 (2001). See also 42 U.S.C.A. § 300aa-23(d)(2).

manufacturers to improve their vaccines.”⁸⁸ The exception reflects a societal judgment that the benefits of developing and distributing these products far exceeds the costs borne by the few injured by such products.⁸⁹ “Among the rationales for this rule is the idea that medical products are of special importance because of their lifesaving qualities. But it is not the social utility of a product that is at issue in traditional fault-based design-defect analysis; it is the designer’s failure to adopt an available, practical, and safer design.”⁹⁰

One commentator suggests a more nuanced approach, rather than blanket immunity that comment k seems to provide vaccine manufacturers, advocating for the three-part test under *Kearl v. Lederle Laboratories*.⁹¹ The *Kearl* test examines: “(1) whether the product was intended to confer a high benefit; (2) whether the then-existing risk of the product was ‘substantial’ and ‘unavoidable’; and (3) whether the interest in availability at the time of distribution outweighs the interest in enhanced accountability.”⁹² These new liability rules in tort litigation cases may influence the manufacturer’s risk-benefit calculation when marketing a vaccine.

However, even with modified liability rules, there will always be some risk of an adverse reaction involved with any drug, since the manufacturer can only invest a reasonable amount to minimize the small probability of an adverse reaction. This decision is made ex ante, designed to minimize the probability of a death, rather than spending a certain amount of money to prevent an identifiable death ex post.⁹³ However, jurors in traditional tort litigation simply compare the loss to the identifiable victim before them “against the costs to save that individual, neglecting the fact that before the accident the loss was only an abstract possibility.”⁹⁴

⁸⁸Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U.L. REV. 1853, 1896 (1995).

⁸⁹See Dan L. Burk and Barbara A. Boczar, *Symposium: Biotechnology and Tort Liability: A Strategic Industry at Risk*, 55 U. PITT. L. REV. 791, 810-811 (1994).

⁹⁰George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?* 109 YALE L.J. 1087, 1133 (2000).

⁹¹218 Cal. Rptr. 453 (Ct. App. 1985).

⁹²Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U.L. REV. 1853, 1900 n.352 (1995), citing *Kearl v. Lederle Laboratories*, 218 Cal. Rptr. 453, 464 (Ct. App. 1985).

⁹³See W. Kip Viscusi, *Corporate Risk Analysis: A Reckless Act?* 52 STAN. L. REV. 547 (2000).

⁹⁴*Id.* at 587.

One commentator applauds these restrictions on tort liability: “Immunities and liability limits are the public risk equivalents of Good Samaritan laws.”⁹⁵

Second, many argue that shielding manufacturers from tort liability through the learned intermediary doctrine may in fact encourage research and development. “By allowing vaccine manufacturers to convey adequate warnings to consumers through contractual obligations with reliable third parties, pharmaceutical companies may concentrate on what they do best—researching and marketing new and much-needed vaccines.”⁹⁶ However, the learned intermediary may be insufficient to ensure that parents receive information about the possible adverse effects of vaccines, and vaccine manufacturers or health care providers should be required to directly inform patients of these risks. This information would not only influence their decision to have their children vaccinated, but would also empower them with the knowledge necessary to recognize possible symptoms and inform their physician of their child’s recent vaccinations. All of this could facilitate earlier diagnoses and subsequent treatment to minimize the damage of any adverse reaction to the vaccine. Direct warnings to patients is required in mass immunization clinics, where courts have found that the setting lacks a physician’s individual assessment of the risks and benefits of vaccination. Therefore, those administering the vaccines are required to inform patients of the risks in these settings, and therefore, the learned intermediary doctrine could be eliminated in all settings where vaccinations are given to children.⁹⁷

Some argue that the learned intermediary doctrine goes against the very essence of patient autonomy and

⁹⁵Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 330 (1985).

⁹⁶Beth L. Eskin, *Immunizations, Learned Intermediaries, and the Manufacturer’s Duty to Warn: Mazur v. Merck & Co., Inc.*, 38 VILL. L. REV. 1297, 1316 (1993).

⁹⁷See Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U.L. REV. 1853, 1863 n.69 (1995), citing *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1277 (5th Cir.), cert. denied, 419 U.S. 1096 (1974); *Davis v. Wyeth Lab.*, 399 F.2d 121, 131 (9th Cir. 1968). But see *Walker v. Merck & Co.*, 648 F. Supp. 931, 934 (M.D. Ga. 1986), aff’d, 831 F.2d 1069 (11th Cir. 1987) (limiting *Reyes* and *Davis* holdings to polio vaccines); *Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1324 (Kan. 1986) (holding that the learned intermediary doctrine only applies to physicians who administer the vaccine).

informed consent, since the physician is only required to inform the patient of the risks that the medical community deems reasonable to disclose under the “customary practice standard.” If there is any problem with informed consent, “it seems more to do with the failure to observe that legal duty rather than a lack of legal obligation.”⁹⁸ Because the success of vaccination programs has significantly decreased the risk of naturally contracting the illness, the risk of being seriously injured by the vaccine itself becomes material information and very much relevant to the parent’s informed decision on the value of the vaccination.⁹⁹

However, physicians are often reluctant to disclose all of the possible adverse effects because most are extremely rare and the benefits of vaccination greatly outweigh infrequent yet significant risks associated with vaccines. Parents may not understand that the “effective control of communicable diseases depends on immunizing a high percentage of the population.”¹⁰⁰ One statistic estimates that at least 11 percent of vaccinated children contracted their case of measles from someone who opted out of the vaccination program.¹⁰¹ Because many of the adverse risks cannot be “linked in advance to any particular class of patients, individualized medical knowledge of the patient could not have decreased these risks.”¹⁰² A government-mandated vaccination program that protects vaccine manufacturers and health care providers from giving direct warnings of the risk of rare adverse events may be needed to minimize moral hazard problems. States often intervene over parental consent in many areas of the law, exercising their *parens patriae* power when doing so is in the best interests of the child and for society as a whole.

⁹⁸MANITOBA LAW REFORM COMMISSION, COMPENSATION OF VACCINE-DAMAGED CHILDREN 41 (2000).

⁹⁹See Andrea Peterson Woolley, *Informed Consent to Immunization: The Risks and Benefits of Individual Autonomy*, 65 CALIF. L. REV. 1286, 1301 (1977).

¹⁰⁰See *id.* at 1310.

¹⁰¹See Ross D. Silverman and Thomas May, *Private Choice Versus Public Health: Religion, Morality, and Childhood Vaccination Law*, 1 MARGINS 505 (2001), citing Daniel R. Feikin, et al., *Individual and Community Risks of Measles and Pertussis Associated with Personal Exemptions to Immunization*, 284 JAMA 3145 (2000).

¹⁰²Andrea Peterson Woolley, *Informed Consent to Immunization: The Risks and Benefits of Individual Autonomy*, 65 CALIF. L. REV. 1286, 1294 (1977).

Because vaccinations are mandatory before children are allowed to enter schools, even if parents knew of the rare risks of vaccines, they may not effectively refuse the vaccination unless they have a religious¹⁰³ or philosophical¹⁰⁴ objection, or the vaccine is contraindicated for the child. The duty to disclose and the doctrine of informed consent are based on the desire to preserve individual autonomy.¹⁰⁵ “One gives an informed consent to an intervention if and only if one receives a thorough disclosure about it, one comprehends the disclosure, one acts voluntarily, one is competent to act, and one consents to the intervention.”¹⁰⁶ Unless the parents qualify for one of the state exemptions, they may not be able to refuse vaccinating their child even if they are aware of the risks.

However, “no interest is served by ... withholding information. Actions of that nature enhance anxiety, create suspicion and generate criticism, all of which ultimately undermine public confidence and support in the immunization system. The immunization program is only strengthened by a transparency of its purpose, risks and benefits.”¹⁰⁷ Therefore, the more common adverse risks or at least those delineated in the Table should be disclosed to parents before vaccination.

Finally, critics argue that the presumption in favor of pharmaceuticals that comply with FDA warnings is insufficient to protect consumers from the adverse effects of vaccines. “Given that the FDA only evaluates

¹⁰³All states allow a religious exemption from vaccinations, except for Mississippi and West Virginia. See Ross D. Silverman and Thomas May, *Private Choice Versus Public Health: Religion, Morality, and Childhood Vaccination Law*, 1 MARGINS 505 (2001).

¹⁰⁴17 states currently allow a moral or philosophical exemption from vaccines: Arizona, California, Colorado, Idaho, Louisiana, Maine, Michigan, Minnesota, New Mexico, North Dakota, Ohio, Oklahoma, Rhode Island, Utah, Vermont, Washington, and Wisconsin. See *General Vaccine Exemption Questions*, at <http://home.san.rr.com/via/states/vaxexemptions.htm>.

¹⁰⁵See Andrea Peterson Woolley, *Informed Consent to Immunization: The Risks and Benefits of Individual Autonomy*, 65 CALIF. L. REV. 1286, 1295 n.51 (1977).

¹⁰⁶Kristine M. Severyn, *Jacobson v. Massachusetts: Impact on Informed Consent and Vaccine Policy*, 5 J. PHARMACY & LAW 249, 253 (1995), citing Beauchamp, *Informed Consent*, MEDICAL ETHICS 180 (1989).

¹⁰⁷MANITOBA LAW REFORM COMMISSION, COMPENSATION OF VACCINE-DAMAGED CHILDREN 42 (2000).

warnings based on the information submitted by manufacturers, the FDA's role in the warning evaluation process is somewhat 'passive.' ... The warnings approved by the FDA, therefore, may not represent the safest potential warnings, for the FDA may not have considered the full universe of relevant information."¹⁰⁸ Only five states have accepted compliance with FDA requirements as a defense against punitive damages in tort litigation.¹⁰⁹

However, the U.S.'s FDA approval process is one of the most rigorous in the world, and no drug that affects the human body physiologically and biochemically will ever be 100 percent safe. When adverse effects are on the order of affecting 1 in every million children,¹¹⁰ the risks involved in any given vaccine will almost never be illuminated during the clinical trials, which at most, test tens of thousands of children in a time span of a few years.¹¹¹ "The labeling of a product as 'safe' by a regulatory agency, therefore, must mean 'safe enough,' which implies that the regulatory process entails, implicitly or explicitly, a weighing of benefits and risks."¹¹² Because the FDA is forced to conduct a cost-benefit analysis for every drug seeking approval, balancing the risks of releasing a drug prematurely with those of delaying the release of a potentially beneficial drug, a government standards defense is often unavailable since the regulation often represents a floor of safety below which a manufacturer's drug may not fall.¹¹³ However, by engaging in risk allocations through tort litigation, "courts engage in risk allocations that often contravene the judgment of the FDA, the Centers for Disease Control and Prevention, and the consensus of the medical profession."¹¹⁴

¹⁰⁸Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U.L. REV. 1853, 1885 (1995).

¹⁰⁹Those five states are: Arizona, New Jersey, Ohio, Oregon, and Utah. See W. Kip Viscusi, *Corporate Risk Analysis: A Reckless Act?* 52 STAN. L. REV. 547, 581 n.110 (2000).

¹¹⁰An estimated 1 in a million children who receive the measles or mumps vaccines will suffer a serious reaction, including encephalitis. See Michael P. Parillo, *Allison v. Merck & Co.: Products Liability and the Drug Manufacturer*, 4 J. PHARMACY & LAW 245 (1995).

¹¹¹See Mark M. Hager, *Civil Compensation and Its Discontents: A Response to Huber*, 42 STAN. L. REV. 539 (1990).

¹¹²Dan L. Burk and Barbara A. Boczar, *Symposium: Biotechnology and Tort Liability: A Strategic Industry at Risk*, 55 U. PITT. L. REV. 791, 834-835 (1994).

¹¹³See Gregory C. Jackson, *Pharmaceutical Product Liability May be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U.L. REV. 199 (1992).

¹¹⁴Jeffrey O'Connell and Ralph M. Muoio, *The Beam in Thine Eye: Judicial Attitudes Toward "Early Offer" Tort Reform*,

In addition, the FDA and CDC committees that approve and recommend the very vaccines that every child should receive have been criticized to consist of members who have significant conflicts of interests, including patent interests, financial investments, and financial interdependencies with the vaccine manufacturers seeking approval. This might contribute to the public’s weariness and distrust in the FDA’s seemingly impartial and objective assessment of the safety of the drugs awaiting its approval. The Act takes these concerns into account by enabling plaintiffs to rebut the presumption by clear and convincing evidence¹¹⁵ that the manufacturer engaged in fraud or intentional and wrongful withholding of information before or after approval regarding the vaccine’s safety or efficacy,¹¹⁶ or failed to exercise “due care notwithstanding compliance” with FDA regulations.¹¹⁷ In addition, in response to public criticism leading to an investigation by the House Committee on Government Reform,¹¹⁸ the FDA renewed its waiver process, asking more detailed questions of its committee members before allowing them to partake in the committee’s decision-making process.¹¹⁹

Incentives for Pharmaceuticals to Develop Safer Vaccines

The Act’s critics argue that the liability shields and flat tax that funds the program do not give manufacturers sufficient incentives to develop safer and more effective vaccines. When enacted, the excise tax was proportional to the level of risk associated with the vaccine; the more adverse events associated with the vaccine, the higher the tax. However, in 1996, Congress amended the Act, reducing the excise tax to a \$0.75 flat tax due to Congress’s desire to reduce the fund’s surplus. Critics argue that the flat tax is ineffective,

1997 U. ILL. L. REV. 491, 498 (1997).

¹¹⁵42 U.S.C.A. § 300aa-22(b)(2)(B).

¹¹⁶42 U.S.C.A. § 300aa-23(d)(2)(A) and (B).

¹¹⁷42 U.S.C.A. § 300aa-22(b)(2)(B).

¹¹⁸*See, e.g., FACA: Conflicts of Interest and Vaccine Development—Preserving the Integrity of the Process: Hearing Before the House Committee on Government Reform*, 106th Cong. 239 (2000); MAJORITY STAFF OF HOUSE COMM. ON GOVERNMENT REFORM, 106TH CONG., REPORT ON CONFLICTS OF INTEREST IN VACCINE POLICY MAKING (2000).

¹¹⁹*See infra* Appendix B and C for a copy of the FDA’s waiver forms.

since it does not account for risk at all. Further, the flat tax may possibly provide even less incentives for vaccine manufacturers to invest in research and development and give consumers a false impression that all vaccines are equally safe. In addition, it may make the fund vulnerable to bankruptcy if a single batch of vaccine causes a disproportionate number of injuries and claims, since the federal government has no backup source in case claims exhaust the fund.¹²⁰ Instead of analyzing what was causing the mismatch between VICP revenue and compensation awards, Congress may have “foreclose[d] serious considerations of alternative explanations” of the over funding situation.¹²¹ Possible explanations might be outdated risk models that determined the excise tax before the amendments, or less than an optimal number of meritorious claims being awarded.

In addition, according to the Health Resources and Services Administration (“HRSA”), as of March 2003, \$895.0 million (62.8 percent) of approximately \$1.4 billion in awards and attorney fees were from generally appropriated funds, compensating pre-1988 claims, rather than from the excise taxes in the trust fund.¹²² Most of the close to \$1 billion surplus in the trust fund is loaned to the Treasury and used for other federal programs, who then pays interest back to the fund. The Congressional Budget Office (“CBO”) estimates that within the next decade, the surplus will grow to \$2.6 billion, generating three times more revenue than claims paid out and administrative costs.¹²³ Parent groups argue that the large surplus reflects the fact that an insufficient number of claims are being compensated, while vaccine manufacturers claim the surplus shows that the excise taxes are too high.¹²⁴ In addition, the FDA and CDC want to use that surplus to fund

¹²⁰Jaclyn Shoshana Levine, *the National Vaccine Injury Compensation Program: Can It Still Protect an Essential Technology?* 4 B.U. J. SCI. & TECH. L. 9, *63 (1997).

¹²¹*See id.*

¹²²Heath Resources and Services Administration, Office of Special Programs, *National Vaccine Injury Compensation Program: Monthly Statistics Report* (Mar. 31, 2003), at <http://www.hrsa.gov/osp/vicp/monthly.htm>.

¹²³*See* UNITED STATES GENERAL ACCOUNTING OFFICE, REPORT TO THE CHAIRMAN, SENATE COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS, VACCINE INJURY COMPENSATION: PROGRAM CHALLENGED TO SETTLE CLAIMS QUICKLY AND EASILY 18 (1999).

¹²⁴*Id.*

vaccine-related research, including the Vaccine Adverse Event Reporting System (“VAERS”) and general research examining causation links between vaccines and chronic conditions,¹²⁵ risk factors to help predict who will suffer from adverse reactions, and developing safer vaccines. Any changes in how the trust fund surplus is allocated will significantly affect the federal government’s general budget.

¹²⁵ *See id.*

As long as the fund is running a surplus, one commentator proposes giving pharmaceutical companies risk rebates—returns on their contributions of the excise tax, proportional to its safety.¹²⁶ “Since the flat tax will be actuarially set above the minimum revenue needed to run the program, part of the surplus funding would be returned to manufacturers based on how much the VICP paid to petitioners for injuries from that particular manufacturer’s vaccine. The money remaining in the Trust fund after the VICP pays the rebates would be used to expand the VICP’s coverage.”¹²⁷ The actual amount paid in taxes would be proportional to the number of doses a manufacturer produces. Therefore, each manufacturer would contribute to the fund in proportion to its total share in the vaccine market, including all of the vaccines it produces. Higher rebates would go to those manufacturers with the safest vaccines; however, higher rebates might, in turn, go to those who have less well-known side effects and therefore, harder to establish claims, and produce perverse incentives. The effect such rebates would have on manufacturers’ behavior is difficult to predict. On the one hand, the risk rebate system may potentially have some disincentives for manufacturers from producing riskier vaccines. At the same time, it may also give them incentives to make those particular vaccines safer and more efficacious.

Some argue that the risk rebate system altogether goes against the spirit of the NVICP, since the main purpose of a no-fault compensation program is to compensate those injured by the vaccines, rather than assigning costs to the vaccine manufacturer who may or may not be at fault. Calabresi argues that coupling damages and compensation with the behavior of the individual injurer is deeply flawed. “If no activity—whether injurer, victim, or mixed—were statistically linked to greater accident proneness, the fund-tax would automatically, *by definition* almost, become a general one, and the accident risk would automatically be treated as a socialized risk of living.”¹²⁸

In Calabresi’s opinion, a better approach is that taken by Sweden, which requires vaccine manufacturers to

contribute directly to a fund established by voluntary agreement with a consortium of insurance companies who jointly wanted to establish a scheme that complemented the country's existing medical insurance programs.¹²⁹ The Swedish Pharmaceutical Insurance's funding is based entirely on levies on the pharmaceutical industry. In 1986, the premium for the insurance amounted to approximately \$2.4 million, corresponding to about 0.4 percent of the industry's total business volume in Sweden.¹³⁰ According to Calabresi, "the clearest advantage is that by employing essentially private insurance devices and rates that are presumably actuarially set, the Swedish approach avoids the danger of hidden political tinkering with the amounts charged to risk-prone categories."¹³¹ Calabresi strongly favors having private insurers make presumably objective decisions based on actuarially based assessments, rather than American politicians making tax assessment decisions based on special interest groups and other governmental pressures. In his opinion, Sweden's approach best accomplishes most of the general goals of accident law: deterrence, compensation, distributing burdens of accident and safety costs on those most suited to bear them by reason of wealth or status in society, and efficiency.¹³²

¹²⁹See Gregory C. Jackson, *Pharmaceutical Product Liability May be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U.L. REV. 199 (1992).

¹³⁰See Carl Oldertz, *Security Insurance, Patient Insurance, and Pharmaceutical Insurance in Sweden*, 34 AM. J. COMP. L. 635, 654 (1986).

¹³¹Guido Calabresi, *Policy Goals of the "Swedish Alternative,"* 34 AM. J. COMP. LAW 657, 662 (1986).

¹³²See *id.* at 658. For a more detailed discussion of Sweden's compensation program, see *infra* Comparisons with Other Vaccine Compensation Programs.

NVICP's Successes

Legislative intervention almost always has important consequences that lawmakers were unable to foresee and predict—consequences which may become foreign to the original legislative purpose.¹³³ Many critics believe that the NVICP has become such an intervention. However, “despite the criticisms, no commentator has argued that Congress should repeal the NVICP. . . . All things considered, . . . the NVICP appears superior to relying on the tort system alone.”¹³⁴

One of the main criticisms of the program is that it has become as adversarial as the tort system it aspired to replace. “Program participants have ‘traded’ Department of Justice counsel in place and stead of pharmaceutical industry defense counsel, the attorneys they would have faced in traditional litigation.”¹³⁵ However, there are distinct differences that the program tries to implement to reduce the adversarial nature and thus, the litigation costs incurred by both parties.

One such approach is a lax discovery process. For example, special masters use “Rule 5 conferences”¹³⁶ to meet with both parties and their respective counsel after reviewing the reports from both the plaintiff and the DOJ. During this conference, the special master: “(1) gives each party an opportunity to address the other’s position, (2) states a tentative view as to the merits of the case, and (3) establishes with the parties what issues remain to be addressed and the most efficient means for deciding those issues.”¹³⁷ Because

¹³³See Philip Shuchman, *It Isn’t That the Tort Lawyers Are So Right, It’s Just that the Tort Reformers Are So Wrong*, 49 Rutgers L. Rev. 485, 491 n.29 (1997).

¹³⁴Keith M. Garza, *Administrative No-Fault Recovery for Transfusion-Related HIV Infection*, 60 Def. Couns. J. 384, 388 (1993).

¹³⁵Kristine M. Severyn, *Jacobson v. Massachusetts: Impact on Informed Consent and Vaccine Policy*, 5 J. PHARMACY & LAW 249, 265 (1995).

¹³⁶The Vaccine Rules of the U.S. Court of Federal Claims govern all proceedings before the Office of Special Masters or any judge on the Court of Federal Claims under the NVICP. Vaccine Rule 5 gives special masters guidelines for conducting this “pre-trial” conference. See RULES OF THE UNITED STATES COURT OF FEDERAL CLAIMS, APPENDIX J, VACCINE RULE 5 (2001).

¹³⁷OFFICE OF SPECIAL MASTERS, UNITED STATES COURT OF FEDERAL CLAIMS, GUIDELINES FOR PRACTICE UNDER THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 9 (2002).

the pretrial discovery process is one of the most expensive aspects of tort litigation,¹³⁸ presumably this “pre-trial” conference facilitates resolution and minimizes strategic litigation tactics.

In addition, over the history of the NVICP, special masters have reversed approximately 44 percent of the post-1988 cases (and roughly 30 percent of pre-1988 cases) that the PHS branded as non-compensable and the DOJ argued before a special master.¹³⁹ For post-1988 claims, from FY 1989 to FY 2003 (through March 31, 2003), 3,976 claims were filed, of which 1,400 (35.2 percent) were adjudicated. Of the 1,400 claims adjudicated, 613 (43.8 percent) were awarded some compensation, while the rest were dismissed. For pre-1988 claims, from FY 1989 to FY 2003 (through March 31, 2003), 4,267 claims were filed, of which 4,252 (99.6 percent) were adjudicated. Of the 4,252 claims adjudicated, 1,185 (27.9 percent) were compensated, the rest dismissed.¹⁴⁰ This conclusion assumes that claims that the PHS recommended to be compensated were not further adjudicated, and those dismissed were ruled in favor of the DOJ or otherwise found non-compensable.

Perhaps one of the most striking successes of the program is the relative lack of substantive case law regarding the NVICP. As of December 1995, of the 3,337 cases where a special master’s judgment was entered, only twenty-six plaintiffs had filed elections to reject the special master’s judgment.¹⁴¹ Therefore, to the extent that fear of tort liability drove manufacturers out of the market, the program has succeeded in inducing them to continue producing vaccines. No commercial vaccine manufacturer has ceased vaccine production since 1990, and wholesale prices of vaccines have declined.¹⁴² Therefore, the long-term vaccine supply is no

¹³⁸ See Philip Shuchman, *It Isn’t That the Tort Lawyers are so Right, It’s Just that the Tort Reformers are so Wrong*, 49 RUTGERS L. REV. 485 (1997).

¹³⁹ See OFFICE OF INSPECTOR GENERAL, THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM: A PROGRAM REVIEW 15 (1992).

¹⁴⁰ Heath Resources and Services Administration, Office of Special Programs, *National Vaccine Injury Compensation Program: Monthly Statistics Report* (Mar. 31, 2003), at <http://www.hrsa.gov/osp/vicp/monthly.htm>.

¹⁴¹ See MOLLY TREADWAY JOHNSON, ET AL., FEDERAL JUDICIAL CENTER, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 23 (1998).

¹⁴² See Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD DRUG L.J. 351, 357 (2001).

longer a public health concern and those given are safer. “While there are still not many companies involved in vaccine research and production, vaccines for all the common childhood diseases are widely available. The current public health concern is getting parents to get their children vaccinated, not the availability of vaccines.”¹⁴³

In addition, most of the more dangerous vaccines have been modified to reduce adverse risks even further. For example, thimerosal-free vaccines (thimerosal has been suspected to be linked to autism)¹⁴⁴ and acellular pertussis vaccines (the whole cell pertussis vaccine accounts for the majority of adverse reactions reported and compensated under the program)¹⁴⁵ are now given to all children.

Finally, Congress amended the Act in 1998 to eliminate the requirement that plaintiffs could file claims only if they incurred more than \$1,000 in unreimbursable expenses.¹⁴⁶ Courts had previously upheld the constitutionality of this requirement under the Fifth Amendment equal protection clause, since “as a general matter, those who incur only modest expenses or whose expenses are reimbursed from other sources present less compelling cases for compensation than those who incur large, unreimbursed expenses.”¹⁴⁷ Nevertheless, Congress amended the Act in order to lessen the burden on indigent families who did not meet the previous

¹⁴³William M. Brown, *Déjà Vu All Over Again: The Exodus from Contraceptive Research and How to Reverse It*, 40 BRANDEIS L.J. 1, 45 (Fall 2001).

¹⁴⁴In Spring 2002, due to the large number of claims alleging that vaccines had caused autism in their children, the Office of Special Masters established a special procedure to handle these cases, known as Omnibus Autism Proceeding. Guidelines for these proceedings can be found in the Autism General Order #1. See OFFICE OF SPECIAL MASTERS, UNITED STATES COURT OF FEDERAL CLAIMS, GUIDELINES FOR PRACTICE UNDER THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 5 (2002).

¹⁴⁵One figure estimates that 1 in 1,750 children receiving the whole cell version of the pertussis shot will go into convulsions or become unresponsive. See Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD DRUG L.J. 351, 353 n.25 (2001). However, the overall reporting rate of adverse reactions decreased substantially after the acellular pertussis vaccine replaced the whole cell vaccine in 1996, from 26.2 to 12.5 reports per 100,000 net doses distributed. See Center for Disease Control, *Surveillance for Safety After Immunization: The Vaccine Adverse Event Reporting System (VAERS) – United States, 1991-2001*, 52 MORBIDITY AND MORTALITY WEEKLY REP. 1,4 (Jan. 24, 2003).

¹⁴⁶See 42 U.S.C.A. § 300aa-11(c)(1)(D)(i), amended by PUB.L. 105-277, § 1502 (1998).

¹⁴⁷Victor E. Schwartz, Mark A. Behrens and Leavy Mathews III, *Federalism and Federal Liability Reform: The United States Constitution Supports Reform*, 36 HARV. J. ON LEGIS. 269, 297 (1999), citing *Black v. Secretary of Health and Human Services*, 93 F.3d 781, 788 (Fed. Cir. 1996).

requirement.

Recommendations to Improve the NVICP

Although the NVICP is generally successful, it can still be improved in many ways. Any money saved in attorney fees, litigation expenses such as fees to pay experts, and other administrative costs leaves more money in the trust fund for injured victims. For each of the last several years, the total paid from the fund for program administration expenses for the DOJ, HHS, and the Court of Federal Claims has been approximately \$10 million per year.¹⁴⁸ In addition, making the process less adversarial and more generous in granting compensation will help achieve the original legislative intent to help individuals injured by a program that society as a whole benefits from.

A Stronger Focus on Public Policy: A More Relaxed Approach to Scientific Causation

In areas of medical uncertainty, where it is equally probable that the vaccine or another factor caused the injury, the presumption should be for the plaintiff and compensate the child's injuries. Congressional intent suggested that it was more willing to be overinclusive than underinclusive.¹⁴⁹ This presumption would be similar to that employed in workers' compensation cases, where any benefit of the doubt is resolved in favor of the plaintiff, in accordance with the program's public policy. This would also help alleviate the plaintiff's burden of proof, since failure to show causation is one of the most common reasons for denying

¹⁴⁸See MOLLY TREADWAY JOHNSON, ET AL., FEDERAL JUDICIAL CENTER, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 11 (1998), *citing* Thomas E. Balbier, director, Vaccine Injury Compensation Program, Department of Health and Human Services.

¹⁴⁹See e.g., *The National Vaccine Injury Program: Is It Working as Congress Intended? Hearings Before the Committee on Government Reform*, 107th Cong. (2001).

compensation.¹⁵⁰

In seeking the optimal resolution to disputes, law does not necessarily attempt to reach an answer that comports with objective criteria. Such criteria may enter into the dispute resolution process, but other criteria, such as societal mores or public acceptability will likely dominate the outcome. Indeed, law is often called upon to settle disputes where objective criteria are absent or inconclusive; society cannot be put on hold while better data are gathered.¹⁵¹

Although causation is important, special masters' findings are ultimately public policy decisions informed by technical determinations, rather than based on technical determinations only. This may be particularly difficult in a forum where evidentiary and discovery rules are designed to be lax, causation based on scientific findings is the sole issue in dispute, and the adversarial nature of the tort system is often imported into the proceedings. "Science, as a formal system of proof, cannot offer a precise, complete and consistent description of nature."¹⁵² ... In a scientific worldview composed primarily of probabilistic statements, where a given conclusion is likely one of many within an acceptable range of scientific opinion, this norm also means acknowledging competing interpretations."¹⁵³

Special masters need to remember that "the evidence might not meet the evidentiary standards of the scientific community, but that was not what was required; rather, the plaintiff had only to meet the burden of proof required by the adjudicatory process."¹⁵⁴ Since these proceedings are very similar to traditional court hearings, special masters may be more inclined to focus only on the individual claimant before them, rather than the public policies they are there to uphold—policies that should err on overcompensating injured victims when causation is equally likely to be caused by the vaccine as by some other factor.

The stronger presumption for compensating plaintiffs with less emphasis on proving causation with scientific

¹⁵⁰ See Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD DRUG L.J. 351, 357 (2001).

¹⁵² *Id.* at 825.

¹⁵³ *Id.* at 826.

¹⁵⁴ *Id.* at 820, citing *Wells v. Ortho Phar. Corp.*, 615 F. Supp. 262, 266 (N.D. Ga. 1985), *aff'd*, 788 F.2d 741 (11th Cir. 1986), *cert. denied*, 479 U.S. 950 (1986).

certainty will help reduce the adversarial nature of the proceedings. The Vaccine Rules state that special masters “shall determine the nature of the proceedings, with the goal of making the proceedings expeditious, flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case and creating a record sufficient to allow review of the special master’s decision.”¹⁵⁵ Special masters’ decisions can only be set aside by the United States Court of Federal Claims if the decision is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,”¹⁵⁶ making it even more important to make the proceedings at the special master level as least adversarial as possible. The adversarial nature of the legal system including judges and lawyers should play a smaller role in the process of determining public safety.¹⁵⁷ “A more relaxed approach to scientific causation is justified by the objectives of the NCVIA and the understanding of how difficult causation is to prove in these cases.”¹⁵⁸

This approach is also important, since special masters who place too much emphasis on uncertain scientific data may base their decisions on a sort of “pseudo-science of ‘vaccine-ology’”¹⁵⁹ that may lend more credence to the scientific evidence than it otherwise deserves. One commentator criticizes the program for invoking legislation that institutionalizes “specific” causation, providing compensation for some injuries not yet scientifically proven to be associated with the vaccines (lack of general causation).¹⁶⁰ However, the legal decision to provide compensation is not solely based on scientific evidence; policy considerations in motivating parents to have their children vaccinated and protecting vaccine manufacturers from tort liability to ensure a steady vaccine supply may justify overcompensating “undeserving” individuals. Legal rules regarding burdens of proof, legal presumptions, and evidentiary standards almost certainly “alter the outcome of a legal proceeding from that which might have resulted if the court only considered scientific opinions.”¹⁶¹

¹⁵⁵See RULES OF THE U.S. COURT OF FEDERAL CLAIMS, APPENDIX J, VACCINE RULE 3(b) (2001).

¹⁵⁶See 42 U.S.C.A. §300aa-12(e)(2)(B).

¹⁵⁷See Gregory C. Jackson, *Pharmaceutical Product Liability May be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U.L. REV. 199 (Fall 1992).

¹⁵⁸Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD DRUG L.J. 351, 364 (2001).

¹⁵⁹*Id.* at 352.

¹⁶⁰See Derry Ridgway, *Innocent of Empirical Rigor*, 14 ST. THOMAS L. REV. 165, 204 (2001).

¹⁶¹Dan L. Burk and Barbara A. Boczar, *Symposium: Biotechnology and Tort Liability: A Strategic Industry at Risk*, 55 U.

A New Role for Special Masters

Although there is no requirement that special masters be legally trained,¹⁶² all special masters to date have been lawyers. This may partially be due to the fact that they are all appointed by a majority of the judges on the United States Court of Federal Claims.¹⁶³ In addition, perhaps attorneys trained and experienced in balancing legal rules and scientific evidence with public policy may be the best adjudicators of NVICP claims. Special masters who are only trained in the sciences or medical profession may tend to focus even more on the scientific evidence of causation and lose sight of the public policy they are appointed to uphold.

However, special masters should receive some training on the subject matter and be required to remain abreast of the newest technological and medical developments. The eight special masters initially appointed at the NVICP's inception "attended a two-day educational program sponsored by the Federal Judicial Center to familiarize them with the medical issues they would encounter in the program. Those who were appointed later did not receive any specialized training."¹⁶⁴ Special masters themselves believe that "increased familiarity with the scientific and medical issues was very helpful, particularly with respect to helping them focus in on the critical issues in a case."¹⁶⁵ In addition, the specialized knowledge and experience would enable them to ask more probative questions of the experts and other relevant testimonies.

However, one needs to minimize the risk of special masters substituting their "perceived knowledge for evi-

PITT. L. REV. 791, 820 (1994).

¹⁶²See MOLLY TREADWAY JOHNSON, ET AL., FEDERAL JUDICIAL CENTER, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 14 (1998). Congress stated that since "no-fault vaccine compensation proceedings raise fewer legal issues than issues of medicine, . . . masters need not be lawyers by training." H.R. CONF. REP. NO. 101-386, at 515 (1989), *reprinted in* 1989 U.S.C.C.A.N. 3018, 3118.

¹⁶³The court appoints each special master (never more than eight) to a four-year term, subject to removal only for incompetence, misconduct, neglect of duty, or physical or mental disability. See 42 U.S.C.A. § 300aa-12(c)(1), (2), and (4).

¹⁶⁴MOLLY TREADWAY JOHNSON, ET AL., FEDERAL JUDICIAL CENTER, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 15 (1998).

¹⁶⁵*Id.* at 41.

dence.”¹⁶⁶ By employing a panel of appointed experts instead of relying on the respective parties’ experts and the special masters’ individual knowledge and expertise, special masters may be better able to accord proper weight to scientific findings without abdicating all responsibility in reaching an acceptable resolution by “enthroning the scientist as decisionmaker,”¹⁶⁷ and uphold the NVICP’s public policies.

Appointing a Neutral Panel of Experts

One commentator argues that although an appointed, impartial expert would be both more efficient and less costly, “as long as the system remains adversarial and the evidence of causation so controversial, however, this is not a reasonable solution.”¹⁶⁸ However, because causation is so controversial, appointing experts to determine whether or not the vaccine caused the plaintiff’s injuries is not only reasonable, but one that will minimize the adversarial nature of the special master proceedings and reduce general costs to the plaintiffs and government, leaving more money available in the compensation fund for the victims.

In Germany, civil court judges select experts using lists of professionals deemed appropriate to serve as experts assembled by professional licensing bodies or quasi-public bodies.¹⁶⁹ Presumably, special masters in the United States could employ the FDA, CDC, ACCV, or professional medical societies (such as pediatric neurology) to generate lists of professionals who could serve on a panel to determine whether the injuries were caused by the vaccine and not by any other pre-existing condition. There are also a few programs that were recently developed to help identify scientists, physicians and engineers who were willing to serve as

¹⁶⁶*Id.* at 43.

¹⁶⁷Dan L. Burk and Barbara A. Boczar, *Symposium: Biotechnology and Tort Liability: A Strategic Industry at Risk*, 55 U. PITT. L. REV. 791, 821 (1994).

¹⁶⁸Lisa J. Steel, *Note: National Childhood Vaccine Injury Compensation Program: Is This the Best We Can Do for Our Children?* 63 GEO. WASH. L. REV. 144, 172 (1994).

¹⁶⁹ERIC D. GREEN, ET AL. PROBLEMS, CASES, AND MATERIAL ON EVIDENCE 931 (2000).

court-appointed experts. The American Association for the Advancement of Science (“AAAS”) is designed to receive requests for assistance from federal judges and attempts to identify suitable experts for their specific needs and cases. In addition, the Private Adjudication Center at Duke University “has developed a registry of scientific and technical advisors to assist federal and state courts, agencies, arbitrators, mediators, and others who seek assistance in resolving complex scientific and technical issues,” with a focus on medical experts.¹⁷⁰

From this list of professionals, however generated, a pool of fifteen experts would be randomly selected, of whom three would be selected to serve on the panel in a voir dire process similar to the jury selection process, where each party’s counsel has the opportunity to question each prospective expert and exercise a limited number of peremptory challenges. A voir dire process enables the parties to inquire about any conflicts of interest the experts may have,¹⁷¹ and require that any such conflicts be put on record to estop parties from objecting after the proceedings have commenced and constitute an implied waiver. Those selected would be mandated to serve on the panel (similar to jury duty, unless extraordinary circumstances or substantial conflicts of interests prevent the expert from serving) and be given reasonable compensation.¹⁷² This would reduce litigation costs significantly, since experts and other miscellaneous expenses can reach \$10,000 or more,¹⁷³ leaving more money in the fund for the victims.

A voir dire process ultimately leads to more procedural fairness and neutrality, rather than delegating

¹⁷⁰LAURAL L. HOOPER, JOE S. CECIL, THOMAS E. WILLGING, FEDERAL JUDICIAL CENTER, NEUTRAL SCIENCE PANELS: TWO EXAMPLES OF PANELS OF COURT-APPOINTED EXPERTS IN THE BREAST IMPLANTS PRODUCTS LIABILITY LITIGATION 95 n.109 (2001).

¹⁷¹All potential experts could be asked to disclose any conflicts of interests using forms similar to those used by Judge Pointer in *In re Silicone Gel Breast Implants Products Liability Litigation*, MDL-926, 793 F. Supp. 1098 (J.P.M.L. 1992), *infra* Appendix A, or the FDA waiver form, used for members serving on its various committees, *infra* Appendix B and C.

¹⁷²NVICP could use a fee schedule similar to that of the Judge Pointer’s panel discussed *infra*, compensating experts at \$200 per hour. Alternatively, experts could be compensated similar to Judge Finesilver’s panel, discussed *infra*, at \$1,500 per case. In comparison, fees for experts and other litigation costs under the current system can run up to over \$10,000 per case, *infra* note 173.

¹⁷³Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD DRUG L.J. 351, 361 (2001).

that power only to the special master, whose favorable past experience with particular experts may lead to systemic biases. The legitimacy of the appointment of the panel of experts would be maintained by having both parties have some control over the composition of the panel, including making the sources of possible candidates known.¹⁷⁴ “Such participation should give the parties confidence in both the expertise and neutrality of the candidate and enhance the legitimacy of the appointment.”¹⁷⁵

Using court-appointed experts would also maximize institutional competencies between scientists and special masters. According to one survey, most of the special masters reported that they consulted medical textbooks and other medical literature to learn more about the specific issues in their cases. “All indicated that they sometimes consult information not presented by the parties to resolve questionable or conflicting scientific or medical testimony.”¹⁷⁶ However, this role may be more appropriate for a neutral panel of experts, rather than having the special master, who is most likely an attorney not trained in science or medicine, to resolve conflicting scientific or medical evidence.

According to Dr. Marcia Angell, editor of the *New England Journal of Medicine*, “scientific conclusions cannot be based on argument and opinion. There must be data. Yet, in the courtroom, acceptance of expert testimony on scientific questions usually turns on the ‘credibility’ of the witness, not the validity of the evidence on which the witness’s opinion is based.”¹⁷⁷ When presented with conflicting, diametrically opposed opinions, special masters may resort to subjective factors unrelated to the scientific probability of whether or not the vaccine caused the plaintiff’s injury, such as the expert’s demeanor, personality, or reputation

¹⁷⁴See Margaret G. Farrell, *Coping with Scientific Evidence: The Use of Special Masters*, 43 EMORY L.J. 927 (1994).

¹⁷⁵LAURAL L. HOOPER, JOE S. CECIL, THOMAS E. WILLING, FEDERAL JUDICIAL CENTER, NEUTRAL SCIENCE PANELS: TWO EXAMPLES OF PANELS OF COURT-APPOINTED EXPERTS IN THE BREAST IMPLANTS PRODUCTS LIABILITY LITIGATION 96 (2001).

¹⁷⁶MOLLY TREADWAY JOHNSON, ET AL., FEDERAL JUDICIAL CENTER, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND CASE-MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 33 (1998). This practice has been upheld by the U.S. Court of Federal Claims on appeal in *Hines v. Secretary of Health and Human Services*, 21 Cl. Ct. 634 (1990). *Id.*

¹⁷⁷Joseph M. Price and Gretchen Gates Kelly, *Junk Science in the Courtroom: Causes, Effects and Controls*, 19 HAMLINE L.R. 395, 398 (1996), *quoting* Marcia Angell, Do Breast Implants Cause Systemic Disease? *Science in the Courtroom*, 330 NEW ENG. J. MED. 1748, 1748 (1994).

as a professional witness. Appointing a neutral panel increases the fairness, affords the parties a sort of “intellectual due process,”¹⁷⁸ and reduces the arbitrariness of opinions and outcomes.

The current system of experts testifying on the respective parties’ behalf creates perverse incentives for lawyers. Expert witnesses are often referred to as “saxophones,” trained to project the “tune” composed by the lawyer.¹⁷⁹ “The more measured and impartial an expert is, the less likely he is to be used by either side.”¹⁸⁰ Cross-examination is designed to attack the expert’s credibility; his reputation as a professional witness; intellectual biases; and possible conflicts of interest with the vaccine in question, rather than the truthfulness of his assertions. “Short of forbidding the use of experts altogether, we probably could not have designed a procedure better suited to minimize the influence of expertise.”¹⁸¹ Since only contested issues of causation are presumably adjudicated, the present system of dueling experts “‘is a practical closing of the doors of justice upon the use of specialized and scientific knowledge.’ ... [W]hen the conflict between the experts is direct and open, ‘the absurdity of our present system is apparent.’”¹⁸²

For example, the child’s own pediatrician often testifies as the plaintiffs’ expert.¹⁸³ As physicians, they most likely testify more as advocates for the child rather than neutral experts, since physicians are trained to act only in the patient’s best interests and would not have otherwise been hired in the first instance if they were not willing to testify accordingly. They may get “caught up in the adversary system ... and push their conclusions to the very edge of acceptable scientific practice, or even beyond.”¹⁸⁴ Intellectual biases among the experts would presumably be balanced on the panel so that the special master will receive a spectrum

¹⁷⁸Scott Brewer, *Scientific Expert Testimony and Intellectual Due Process*, 107 YALE L.J., 1535 (1998).

¹⁷⁹ERIC D. GREEN, ET AL. PROBLEMS, CASES, AND MATERIAL ON EVIDENCE 927 (2000).

¹⁸⁰*Id.* at 930.

¹⁸¹*Id.*

¹⁸²W. Kip Viscusi, et al., *The Effect of Products Liability Litigation on Innovation: Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1473 n.130 (1994).

¹⁸³According to one survey, 73 percent of plaintiffs’ attorneys used their clients’ treating physicians as experts in entitlement hearings. See MOLLY TREADWAY JOHNSON, ET AL., FEDERAL JUDICIAL CENTER, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND CASE-MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 31 (1998).

¹⁸⁴Dan L. Burk and Barbara A. Boczar, *Symposium: Biotechnology and Tort Liability: A Strategic Industry at Risk*, 55 U. PITT. L. REV. 791, 826 (1994).

of opinions, rather than each party's expert zealously advocating for their respective viewpoints.

Appointing a neutral panel of experts may also facilitate settlement, as parties are often reluctant to come to an agreement because of divergent expectations of the strengths of their cases. "In complex scientific and technical cases, disparity in the parties' estimates of the plaintiff's probability of success are usually caused by sincere and strongly held divergent views on how a crucial technical issue will be decided.... Unless some additional information causes the parties to reevaluate their experts' confidence in their opinions or the parties' confidence in their experts' opinions, the disparity between the estimates of success will prevent settlement."¹⁸⁵

Court-appointed experts may also encourage special masters to give more appropriate weight to expert testimony in general. According to one special master, he tends to discount repeat experts' testimonies because some repeat experts are "not willing to find an encephalopathy if it hits them in the face."¹⁸⁶ When approximately 50 percent of plaintiffs' attorneys use experts who have testified previously for them in a vaccine program case,¹⁸⁷ special masters are not strongly considering the plaintiffs' expert testimonies in a significant number of cases. On the other hand, court-appointed experts may also gain an "aura of infallibility," a concern the Advisory Committee had when enacting Rule 706 of the Federal Rules of Federal Evidence.¹⁸⁸ Consequently, special masters may rely too heavily on the panel's recommendations and like the current system, put too much emphasis on the scientific evidence as an outcome-determinative factor. However, unlike federal courts, the NVICP would be using a panel of three experts, rather than a single expert, which would reflect differing opinions and minimize this concern, since the panel's main goals are to elucidate conflicting scientific evidence and generate a recommendation in light of the medical uncertainty.

¹⁸⁵ERIC D. GREEN, ET AL. PROBLEMS, CASES, AND MATERIAL ON EVIDENCE 927 (2000).

¹⁸⁶MOLLY TREADWAY JOHNSON, ET AL., FEDERAL JUDICIAL CENTER, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 39 (1998).

¹⁸⁷*See id.* at 31.

¹⁸⁸FED. R. EVID. 706 Advisory Committee's Note. Rule 706 gives federal courts the authority to appoint experts by its own selection or by agreement by the parties. However, it also retains the "dueling expert system" by permitting each party to call its own expert witnesses. *See* FED. R. EVID. 706(d). Rule 706 was modeled after Rule 28 of the Federal Rules of Criminal Procedure.

“The court’s expert can function very much like the author of an academic review by outlining and evaluating management recommendations.”¹⁸⁹ This will emphasize the medical uncertainty concerning causation and remind special masters that they will need to consider more than just the scientific evidence in making their decisions.

Another possible downside to this proposed system may be that the panel selected represents more mainstream views, since presumably the more extreme positions would be eliminated by the attorneys’ peremptory challenges. Although this may lead to more predictable and less arbitrary decisions, it might also exclude cutting-edge scientific theories from the special master’s consideration. Requiring special masters to stay abreast new developments or trusting professional societies to recommend experts in the field doing cutting-edge research may help minimize this risk.

Even though special masters have congressional authority to use court-appointed experts, special masters rarely use them.

[T]he masters may, in some cases, be well-advised to retain independent medical experts to assist in the evaluation of medical issues associated with eligibility for compensation and the amounts of compensation to be awarded. In cases where petitioners assert a theory of vaccine causation of injury and respondents claim other causation, the master may find it most expeditious to receive outside advice rather than attempt a full adversarial proceeding on the question of causation. The Act authorizes such action by the master and the Conferees would encourage its use as appropriate.¹⁹⁰

This is consistent with the language in the Act, stating that special masters “may require the testimony of any person and the production of any documents as may be reasonable and necessary.”¹⁹¹ However, even the Office of Special Master’s *Guidelines for Practice Under the National Vaccine Injury Compensation Program* emphasize that special masters *may* hire or suggest the hiring of their own expert witnesses or

¹⁸⁹Derry Ridgway, *Innocent of Empirical Rigor*, 14 ST. THOMAS L. REV. 165, 230 (2001).

¹⁹¹42 U.S.C.A. § 300aa-12(d)(3)(B)(iii).

neutral medical expert in “unusual” instances. “In general, however, the parties are responsible for the traditional tasks of identifying and developing information supporting or opposing an award, securing and presenting fact witnesses and expert testimony, and meeting their respective burdens of proof.”¹⁹² A similar pattern is seen in judges in civil and criminal courts, who are also given similar authority in respective statutes.¹⁹³

One reason judges cite as to why court-appointed experts are not used in the trial context is to preserve the adversarial nature of the proceedings with minimal judicial intervention. However, in the vaccine injury cases, the special masters are extensively involved from the start, holding pretrial meetings to discuss what sorts of documents should be provided; their initial thoughts about the case; and what further evidence each party needs to show. In this respect, the special masters take on a comparable role to the judges in Europe who are seen as part and parcel of the investigatory process. In addition, the NVICP is designed to minimize the adversarial nature of the proceedings; it was not intended to be yet another litigious trial. Therefore, the NVICP may be an ideal setting to use such experts.

Court-appointed experts have been used in cases where causation of vaccine injuries is to be determined. During what Congress perceived to be a swine flu epidemic in the 1970’s, Congress passed the National Swine Flu Immunization Program of 1976 (the “Swine Flu Act”),¹⁹⁴ insulating insurance companies and vaccine manufacturers from liability and establishing the Federal Treasury as the insurer for adverse effects of the vaccine. The Swine Flu Act was eventually repealed in 1978, although claims continued to be litigated

¹⁹²OFFICE OF SPECIAL MASTERS, UNITED STATES COURT OF FEDERAL CLAIMS, GUIDELINES FOR PRACTICE UNDER THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 8 (2002).

¹⁹³See FED. R. CIV. PRO. 53(b) and (c), which states that court-appointed masters may be appropriate to report on “particular issues or to do or perform particular acts or to receive and report evidence” when the issues are “complicated” or upon “a showing that some exceptional condition requires it.”

¹⁹⁴See Victor E. Schwartz, Mark A. Behrens and Leavy Mathews III, *Federalism and Federal Liability Reform: The United States Constitution Supports Reform*, 36 HARV. J. ON LEGIS. 269 (1999).

through 1990.¹⁹⁵ Of the forty-five million inoculated, 4,169 filed claims for damages were filed against the government by 1986 for injuries caused by the vaccine.¹⁹⁶ Cash settlements were sixty times the original estimates (\$86.3 million) and forty-one lawsuits were still pending ten years after the program's inception.¹⁹⁷ Court-appointed experts were used in one of these cases involving ten plaintiffs. *In re Swine Flu Immunization Products Liability Litigation*,¹⁹⁸ Judge Sherman G. Finesilver (D. Col., sitting on the case by designation) appointed a panel of three medical experts (two neurologists and one medical statistician and epidemiologist) under Rule 706 of the Federal Rules of Evidence.

Due to the technical complexity of certain issues involved in this litigation, the Court finds that the appointment of a Panel of Medical Experts will meaningfully assist in their resolution. We further find that the medical findings and conclusions of said Panel may significantly enhance settlement negotiations between the litigants and potentially lead to resolution of these cases without necessity of trial.¹⁹⁹

The panel itself then appointed a Chairperson and two members who would conduct physical examinations on the plaintiff to determine whether the swine flu vaccine caused the plaintiff's injury. Judge Finesilver delineated the panel's "areas of inquiry" as: "(1) the nature and extent of the injuries suffered by plaintiff; (2) the causal connection, if any, between the injuries and the immunization; (3) the prognosis of plaintiff's condition and prospects for rehabilitation; and (4) the nature and extent of treatment which plaintiff will be required to undergo."²⁰⁰ Where the panel determined that the plaintiff's injury was not Guillain-Barre Syndrome (the condition associated with the swine flue vaccine), the panel would also address: "(5) what was known in the medical community prior to October 1976 about the causal relation between influenza immunization and the injury plaintiff contracted."²⁰¹ After examining the plaintiff and all of the relevant

¹⁹⁵See Keith M. Garza, *Administrative No-fault Recovery for Transfusion-Related HIV Infection*, 60 DEF. COUNS. J. 384 (1993).

¹⁹⁶John P. Wilson. *The Resolution of Legal Impediments to the Manufacture and Administration of an AIDS Vaccine*, 34 SANTA CLARA L. REV. 495, 506 (1994).

¹⁹⁷*Id.*

¹⁹⁸495 F. Supp. 1185 (W.D. Okla. 1980).

²⁰⁰*Id.*

²⁰¹*Id.*

medical records and documents, the panel submitted a single report of its findings on the above areas of inquiry, along with any dissenting reports to the court and respective parties by the court's set deadline. After submitting the report, each party had 10 days to request the deposition of any panel member, as well as examine and cross-examine any panel member at trial. The party requesting the panel member's deposition and trial testimony was responsible for the additional cost (otherwise, each panel member was paid \$1,500 per case).²⁰²

In mass torts litigation regarding silicone breast implants, Chief Judge Sam C. Pointer, Jr. (N.D. Ala.),²⁰³ designated to handle pretrial proceedings in a multi-district litigation, *In re Silicone Gel Breast Implants Products Liability Litigation*, MDL-926,²⁰⁴ appointed a selection panel (consisting of an evidence professor and several scientists)²⁰⁵ to screen individuals who would serve on the National Science Panel (under Rule 706), charged with the following written instructions:

(a)

Issues. To what extent, if any, and with what limitations and caveats do existing studies, research, and reported observations provide a reliable and reasonable scientific basis for one to conclude that silicone-gel breast implants cause or exacerbate any of the conditions described in (b) below? If, in the process of making these findings, you believe that there are related or subordinate issues that should be separately addressed, please do so.

(b) Scope. You are asked at this time to consider the relationship, if any, between implants and the following:

²⁰²*Id.* at 1187.

²⁰³Judge Pointer's decision to use court-appointed experts seemed to be inspired by Judge Weinstein's use of Rule 706 panels of experts in silicone breast implant cases before him in the Eastern District of New York. His selection panel consisted of two attorneys and one scientist, appointed as special masters under FED. R. CIV. PRO. 53, to select a science panel and consider what the scope of their work might be. *See* PAUL D. RHEINGOLD, MASS TORT LITIG. § 11:9 (2002).

²⁰⁴793 F. Supp. 1098 (J.P.M.L. 1992).

²⁰⁵*See* PAUL D. RHEINGOLD, MASS TORT LITIG. § 11:9 (2002).

- i) “classic” connective tissue diseases, such as systemic lupus erythematosus, Sjögren’s syndrome, etc.
- ii) “atypical” presentations of connective tissue diseases or symptoms
- iii) immune system dysfunctions

(c) Contrary Opinions. To what extent, if any, should any of your opinions referenced in (a) above be considered as subject to sufficient genuine dispute as would permit other persons, generally qualified in your field of expertise, to express opinions that, though contrary to yours, would likely be viewed by others in the field as representing legitimate and responsible disagreement within your profession?²⁰⁶

Based on the selection panel’s recommendations, Judge Pointer ultimately appointed four experts from each of the four relevant disciplines (toxicology, epidemiology, rheumatology, and immunology) to serve on the National Science Panel.²⁰⁷ He also appointed special counsel to represent the experts’ interests, facilitate communication among the panel members, and help familiarize them with the legal proceedings.²⁰⁸

The experts were asked to comment or seek clarification from the court’s instructions before commencing with its duties; none expressed any reservations over the instructions. Judge Pointer’s panel submitted one report, with each expert writing his own chapter, linked by a common executive summary. Each chapter contained its own background, definitions of problems, analyses, references, and conclusions. The panel’s report would then become part of the record of 22,000 breast implant cases that had been consolidated in Judge Pointer’s court as part of the multi-district litigation process.²⁰⁹ In addition, each party was free to call its own experts during trial.

The three-year process of selecting, instructing, deposing, and reporting by the panel members cost \$1 million,²¹⁰ which was funded in part, by the federal judiciary, as well as by the respective parties. Judge Pointer

²⁰⁷See *id.* at 16.

²⁰⁸Experts found this cumbersome and eventually communicated directly with each other. See *id.*

²⁰⁹See *id.* at 82.

²¹⁰See *id.* at 21.

noted that having the judiciary contribute to the panel's expense "would show the court's commitment to resolving difficult legal-scientific questions in a manner that emphasizes truth rather than partisanship or the parties' resources."²¹¹ Each of the selection panel members and the National Science Panel experts were paid \$200 per hour for their work. Fees and expenses associated with the work of the special counsel amounted to over a million dollars.

In comparison, in *Hall v. Baxter Healthcare Corp.*,²¹² Judge Robert Jones (D. Or.) selected a panel of technical advisors from a list consisting of the senior faculty in each specialty area at the Oregon Health Sciences University and from other professional and academic colleagues. He had each technical advisor submit a separate report, therefore requiring little communication among panel members.²¹³ The panel's role was more limited than in the previous two examples. Judge Jones appointed the panel (under Rule 104(a) of the Federal Rules of Evidence, related to the court's threshold in determining the admissibility of testimony) in anticipation of disputes about scientific methodology and admissibility of testimony from the plaintiffs' experts, since the condition in question was an unusual form of connective tissue disease allegedly caused by the migration of silicone from the implants.²¹⁴ The panel was designed to assist the judge in evaluating proffered expert testimony, primarily that of the plaintiffs, and accordingly, to offer advice regarding the admissibility of scientific evidence in motion in limine proceedings.²¹⁵

The effects of the use of court-appointed experts in both breast implant cases are difficult to assess, since most of the claims ultimately settled. Whether this could be attributed to the use of the panel or what the plaintiffs' attorneys thought to be a long and arduous process that forced them to settle is difficult to

²¹¹*Id.* at 82.

²¹²947 F. Supp. 1387 (D. Or. 1996).

²¹³See LAURAL L. HOOPER, JOE S. CECIL, THOMAS E. WILLGING, FEDERAL JUDICIAL CENTER, NEUTRAL SCIENCE PANELS: TWO EXAMPLES OF PANELS OF COURT-APPOINTED EXPERTS IN THE BREAST IMPLANTS PRODUCTS LIABILITY LITIGATION 52 (2001).

²¹⁴See PAUL D. RHEINGOLD, MASS TORT LITIG. § 11:9 (2002).

²¹⁵See LAURAL L. HOOPER, JOE S. CECIL, THOMAS E. WILLGING, FEDERAL JUDICIAL CENTER, NEUTRAL SCIENCE PANELS: TWO EXAMPLES OF PANELS OF COURT-APPOINTED EXPERTS IN THE BREAST IMPLANTS PRODUCTS LIABILITY LITIGATION 87 (2001).

determine. The authors conducting the studies on the panels appointed by Judges Pointer and Jones stated,

The use of court-appointed experts is an extraordinary technique that is appropriate when the evidence is especially demanding and the opportunity for reasoned and principled consideration based on submissions by the parties has been exhausted or offers little promise. The difficulty of accommodating the conflicting values of science and law within such a process is unlikely to satisfy those who insist on the deliberate and openended consideration that is characteristic of science, or those who insist on the speedy and certain resolution of issues that is valued by law.²¹⁶

The authors recommended that future panels should appoint an administrative chair for the panel to help organize the panel's work, helping to facilitate coordination of the panel's collective work and serve as a focus of communication among panel members.

Although the panels in the silicone breast implant litigations were deemed cumbersome and expensive, the NVICP panel of experts would not have to be burdened by the same handicaps. First, in addition to adopting the recommendations by the authors above, Judge Pointer's selection panel and special counsel hired to represent the experts would be unnecessary in the NVICP, since the experts would be selected by a voir dire process. Second, experts would need to familiarize themselves with a simpler set of procedural and evidentiary rules in the NVICP proceedings, in comparison to a complicated multi-district litigation consolidating roughly 22,000 cases. Third, it would be unnecessary to depose each of the experts, as Judge Pointer did, since their report and recommendations would be part of the record, and their testimonies during the proceedings would be subject to questioning by both parties' attorneys and the special master. Finally, because experts would presumably work on a number of claims by virtue of random selection, they would gain an increasing familiarity with the Table and other vaccine-related injuries. In addition, their repeated experiences may even help establish new links between vaccines and injuries that can then be added to the

Table to expand (or restrict, if necessary) coverage under the program.

The National Vaccine Injury Compensation Program Improvement Act of 2003

The National Vaccine Injury Compensation Program Improvement Act of 2003 (the “Improvement Act”) proposes a few changes to improve many aspects of the NVICP.²¹⁷ First, it would increase the current statute of limitations from three to six years from the date of injury. “A relatively generous limitation period is warranted by possible medical uncertainty as to the cause of the death or injury.”²¹⁸ In addition, information about the program is not widely disseminated, and parents may not even be aware of the program without proactively initiating their own research. Although the Improvement Act does not include provisions for equitable tolling for extenuating circumstances, special masters should be given more discretion to hear claims that may fall outside the statute of limitations (whether it be three or six years), especially when there are medical uncertainties of causation present at the time of vaccination.

The following example demonstrates the need for an extended statute of limitations period. One special master rationalized her decision to deny compensation by reasoning that “under an objective standard a reasonable parent would have inquired into her legal rights . . . after seeing such drastic changes in her son’s

²¹⁷In addition to the provisions discussed *infra*, the Improvement Act also provides for a one-time, two-year period for families with post-1988 injuries to file claims if they were previously excluded from filing due to the statute of limitations; increases compensation for future lost earnings, using the Bureau of Labor statistics on the average weekly earnings of full-time workers only (current law includes part-time wages as well); allows for recovery of family counseling costs; and creates and maintains guardianship for the fund. See Congressman Dan Burton, *A Commitment to the Vaccine Injured is Kept: Burton to Introduce “Vaccine Injury Compensation Program Improvement Act of 2003,”* at <http://www.house.gov/burton/pr31803.htm>.

²¹⁸MANITOBA LAW REFORM COMMISSION, COMPENSATION OF VACCINE-DAMAGED CHILDREN 39 (2000).

condition.”²¹⁹ In that case, the child’s “parents made a good faith effort and exercised due diligence in attempting to discover the causes of Alex’s injuries. Why would Alex’s parents [have] thought to pursue legal remedies if they did not even have evidence to prove a causal relationship between his injuries and the vaccination?”²²⁰ If every parent followed the duty as stated by the special master, only absurd results would come, since parents would be encouraged to call their attorneys and think about litigation during a time when they are focusing on trying to make their children healthier.

Second, the Improvement Act would increase the \$250,000 cap on death benefits to \$300,000. The \$250,000 cap on damages has been widely used in tort damages, including medical malpractice, for over twenty years. “The endurance of the \$250,000 figure is especially remarkable given that little thought seems to have gone into devising it in the first place.”²²¹ According to one commentator, the figure was adopted in California at a time when awards rarely exceeded the cap.²²² For the NVICP, the figure has not been adjusted since the program’s inception in 1986, in light of inflation, rapidly increasing medical care costs, and a higher median pain and suffering awards.²²³

Finally, the Improvement Act would modify the schedule of payment of attorneys’ fees. The NVICP provides for reasonable attorneys’ fees, whether or not the plaintiff’s claim is successful, if the claim was brought in good faith and there was a reasonable basis for the claim. However, the special masters have discretion to reduce the fees if they find them unreasonable, and attorneys must wait until a final judgment is rendered—a requirement that sometimes may take years to obtain. Because of the current system’s long and uncertain

²¹⁹Leonard D. Pertnoy, *A Child’s View of Recovery Under the National Childhood Vaccine Act or “He Who Hesitates is Lost,”* 59 MONTANA L. REV. 275, 284 (1998), citing *Pertnoy v. Secretary of Health and Human Services*, No. 95-218V, 1995 WL 579827, at *10 (Fed. Cl. Sept. 18, 1995).

²²⁰*Id.*

²²¹Philip Shuchman, *It Isn’t That the Tort Lawyers are so Right, It’s Just that the Tort Reformers are so Wrong*, 49 RUTGERS L. REV. 485, 539 (1997).

²²²*Id.*

²²³The median pain and suffering award in malpractice cases is now about \$300,000. *Id.*

fee schedule, an increasing number of attorneys are reluctant to accept vaccine cases altogether. One of the proposed amendments in the Improvement Act makes attorneys' fees available during the interim so that attorneys can recover costs while adjudicating their client's claims. This would be similar to experts who can currently recover their expenses within 30 days of rendering their services.

The Need for Additional Research: The Vaccine Adverse Event Reporting System

The NVICA also requires the Secretary to promote the development of vaccines with fewer adverse effects and improve the "licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines."²²⁴ In addition, 42 U.S.C.A. § 300aa-25(b)(1) requires health care providers and vaccine manufacturers to report adverse events to the Secretary. To help facilitate this, the joint administration of the FDA and CDC established the Vaccine Adverse Event Reporting System ("VAERS") in 1990, accepting reports from health professionals, vaccine manufacturers, and the public.²²⁵ "The objectives of VAERS are to 1) detect new, unusual, or rare vaccine adverse events; 2) monitor increases in known adverse events; 3) determine patient risk factors for particular types of adverse events; 4) identify vaccine lots with increased numbers or types of reported adverse events; and 5) assess the safety of newly licensed vaccines."²²⁶

The success of VAERS has been modest at best. The FDA estimates that only ten percent of doctors report such adverse reactions.²²⁷ Vaccine manufacturers file the most reports (36.2 percent), followed by state and local health departments (27.6 percent), health-care providers (20.0 percent), and patients and parents (4.2

²²⁷The CDC estimates that from 1991-2001, 11.4 reports were made per 100,000 net doses distributed for the 27 frequently reported vaccine types. *Id.* at 1 (Jan. 24, 2003).

percent). However, there was a steady increase in the reporting by health-care providers over time, from 11.4 percent in 1991 to 35.3 percent in 2001.²²⁸ The VAERS working group made a conscientious effort to improve the reporting by health-care professionals, including increased education through directed mailing, continuing medical education, and publication of analyses of VAERS data in various medical journals.²²⁹ This increase could have also partly been attributed to new vaccines added in the mid- to late 1990's, including the rotavirus vaccine that has since been shown to cause intussusception in a significant number of infants inoculated with the vaccine.

Unfortunately, the HHS “essentially disregards the system’s [VAERS] importance as an indicator of potential vaccine safety concerns,” attributing such reports as merely “anecdotal.”²³⁰ VAERS receives approximately 10,000 reports per year regarding more than 100 million vaccinations administered to children in the United States. Of all the complaints, approximately 14.2 percent describe serious events, defined as an event resulting in death, life-threatening illness, hospitalization, prolongation of existing hospitalization, or permanent disability.²³¹ The CDC and FDA follow up with any serious report and request additional information, including medical records and autopsy reports, to complete the description of the case.²³² Letters requesting recovery status of persons suffering from serious adverse reactions are also sent to the reporters 60 days and 1 year after vaccination.²³³ Furthermore, a clinical research team follows up with all VAERS reports of death, most of which have been classified as sudden infant death syndrome (“SIDS”). Epidemiological studies have consistently failed to find a causal connection between vaccines and SIDS. However, a causal link may be difficult to establish since a control group of unvaccinated children is virtually impossible to find,

²²⁸*Id.*

²²⁹*Id.* at 4.

²³⁰Kristine M. Severyn, *Jacobson v. Massachusetts: Impact on Informed Consent and Vaccine Policy*, 5 J. PHARMACY & LAW 249, 268 (1995).

²³¹Susan S. Ellenberg and Robert T. Chen, *The Complicated Task of Monitoring Vaccine Safety*, 112 PUB. HEALTH REP. 10 (1997), available at 1997 WL 9736160.

²³²See Center for Disease Control, *Surveillance for Safety After Immunization: the Vaccine Adverse Event Reporting System (VAERS) – United States, 1991-2001*, 52 MORBIDITY AND MORTALITY WEEKLY REP. 1, 2 (Jan. 24, 2003).

²³³*Id.*

and of those who are unvaccinated, they often suffer from other problems such as a lower baseline health and socioeconomic status that are difficult to control for and isolate.

“The lack of enforcement provisions or even any monitoring of reporting practices precludes any assumptions about the extent to which such events are in fact reported.”²³⁴ Because of underreporting, reporting of temporal associations or unconfirmed diagnoses (overreporting), lack of control comparison groups, and differential reporting (VAERS is more likely to receive reports of serious events and those with shorter onset times after vaccination), determining causal connections between the vaccines and the adverse events requires further epidemiological or other laboratory studies.²³⁵ Of more than 1.9 billion doses of vaccines given over an eleven-year period (1991-2001), VAERS only received 128,717 reports of adverse events.²³⁶

However, VAERS is still an important tool to illuminate early signals and possible causal connections that can then be further investigated. Because of the limitations inherent in clinical trials, including a relatively small number of subjects and limited testing period, post-marketing monitoring of adverse events is imperative. VAERS can rapidly identify problems associated with newly licensed vaccines not detected by clinical trials conducted before FDA approval,²³⁷ facilitate lot-specific safety evaluations and initiate recalls if necessary, and reassure the public of the safety of vaccines not associated with significant adverse events. VAERS is the “front line” of vaccine safety surveillance²³⁸ and must be supplemented by further studies and additional research.

New databases of information have also recently being established. The Vaccine Safety Datalink (“VSD”)

²³⁴*Id.*

²³⁵*Id.*

²³⁶*Id.* at 7.

²³⁷VAERS helped to flag the potential causal link between rotavirus vaccines and intussusception for further investigation, leading to the eventual removal of the vaccine from the market.

²³⁸Susan S. Ellenberg and Robert T. Chen, *The Complicated Task of Monitoring Vaccine Safety*, 112 PUB. HEALTH REP. 10 (1997), available at 1997 WL 9736160.

contains information on more than seven million people enrolled in eight health maintenance organizations through the United States. “The strengths of VSD include the documentation of immunizations, the absence of underreporting bias of medical outcomes, and the inclusion in the database of a high number of vaccinated persons who did not have adverse events.”²³⁹ Although VSD does not contain information representative of the population across socioeconomic status, health care setting, and race dimensions, the VSD does permit epidemiological vaccine safety studies to be conducted and new hypotheses tested.

In addition, the CDC established a national network of Clinical Immunization Safety Assessment (“CISA”) Centers that develop and disseminate standardized clinical evaluation protocols to clinicians, and consult and advise health-care providers on the management of patients with adverse reactions and the advisability of continued vaccinations. “The objectives of CISA are to enhance understanding of known serious or unusual vaccine reactions, including the pathophysiology and risk factors for such reactions, as well as to evaluate newly hypothesized syndromes or events identified from the assessment of VAERS data to clarify any potential relation between the reported adverse events and immunization.”²⁴⁰

In addition to building new databases of information, improving the reporting rate by health care providers may be one of the most important objectives of the various surveillance systems. However, a sanction enforcing the statute requiring health care professionals to report adverse events may be a “blunt instrument of public policy in this arena. If there is a problem, it is likely to be a systemic and attitudinal one rather than one that might be neatly and fully resolved by a statutory directive.”²⁴¹ Perhaps the efforts by the VAERS working group in increasing awareness of the importance of the program to health care professionals can help further this goal. In addition, as computer technology makes it possible to put medical records online and

²³⁹See Center for Disease Control, *Surveillance for Safety After Immunization: the Vaccine Adverse Event Reporting System (VAERS) – United States, 1991-2001*, 52 MORBIDITY AND MORTALITY WEEKLY REP. 1, 8 (Jan. 24, 2003).

²⁴⁰*Id.*

²⁴¹MANITOBA LAW REFORM COMMISSION, COMPENSATION OF VACCINE-DAMAGED CHILDREN 43 (2000).

to create vast databases of medical information, adverse events from vaccinations and patient characteristics will naturally be recorded by health care professionals, thus, providing a rich source of invaluable information for vaccine research and development.²⁴²

Comparisons With Other Vaccine Compensation Programs

Surprisingly, many countries with universal health coverage and generous social assistance programs have also implemented separate vaccine injury compensation programs as supplementary sources of compensation. Similarly, the United States' NVICP is designed to be supplementary, placing the burden of proof on plaintiffs to show that their expenses will not be compensated by any "other federal or state health programs (excluding Title XIX of the Social Security Act), private or prepaid health services, insurance policies, or state compensation programs."²⁴³

For example, in determining whether residential placement of the injured child is medical or educational in nature, the special masters determine the source of compensation. The Act covers medical placements only, explicitly prohibiting recovery for punitive or exemplary damages²⁴⁴ or for any other compensation not for the health, education, or welfare of the injured person.²⁴⁵ Therefore, those who need residential placement for "behavioral problems, aggressiveness, potential for self-harm or management problems," even if their condition is caused by a vaccine-related injury, need to be relieved through another state compensation program such as the Individuals with Disabilities Education Act ("IDEA").²⁴⁶ Under the NVICP, "there

²⁴²Presumably, patient privacy (under informed consent and Health Insurance Portability and Accountability Act, or HIPAA, regulations) would be sufficiently protected before research entities could use such information.

²⁴³Susan G. Clark, *The National Vaccine Injury Compensation Program*, 94 ED. LAW REP. 671, 679 (1994).

²⁴⁴See 42 U.S.C.A. § 300aa-15(d)(1).

²⁴⁵See 42 U.S.C.A. § 300aa-15(d)(2).

²⁴⁶IDEA enables children who need special education and related services due to disability to receive a free public education designed to meet their unique learning needs. See Susan G. Clark, *The National Vaccine Injury Compensation Program*, 94 ED. LAW REP. 671, 680 (1994).

is no mandate to maximize potential or provide the best program available, ...or to optimize an injured person's quality of life. Awards under the compensation program are then secondary to relief available under a state compensation program,"²⁴⁷ and not co-extensive with entitlement.²⁴⁸ Consequently, the Act imposes a \$250,000 cap on compensation for pain, suffering, and emotional distress,²⁴⁹ as well as a fixed award of \$250,000 in cases of death.²⁵⁰ Compensation for vaccine-related injuries before October 1, 1988 are much less generous, capping damages at \$30,000 for lost earnings, pain and suffering, *and* reasonable attorneys' fees.²⁵¹

Even though the NVICP is supplementary, the monetary awards are generally higher in the United States than in other countries. The average post-1988 case award in the United States for FY 2003 was \$1,427,169 (out of 40 cases),²⁵² compared to Quebec's average recovery per person of \$135,000²⁵³ and the United Kingdom's lump sum of £40,000²⁵⁴ (approximately \$63,000) paid to each successful applicant, without individual assessments of actual losses. These discrepancies are most likely due to the fact that most other countries provide some form of universal health care coverage that pays for medical expenses that the fund in the United States needs to separately account for. Compensating victims is "an especially acute problem in a nation with such a porous social safety net. ...[W]e need a better system ...so as to be able to say that tort law isn't really needed to provide for accident victims' medical care."²⁵⁵

²⁴⁷*Id.* at 682.

²⁴⁸See Sir Geoffrey Palmer, *The Ninth Monsanto Lecture: The Design of Compensation Systems: Tort Principles Rule, O.K.?* 29 VAL. U.L. REV. 1115 (1995) (discussing New Zealand's vaccine compensation and tort systems).

²⁴⁹See 42 U.S.C.A. § 300aa-15(a)(4).

²⁵⁰See 42 U.S.C.A. § 300aa-15(a)(2).

²⁵¹See 42 U.S.C.A. §300aa-15(b)(1)-(3).

²⁵²Heath Resources and Services Administration, Office of Special Programs, *National Vaccine Injury Compensation Program: Monthly Statistics Report* (Mar. 31, 2003), at <http://www.hrsa.gov/osp/vicp/monthly.htm>.

²⁵³See MANITOBA LAW REFORM COMMISSION, COMPENSATION OF VACCINE-DAMAGED CHILDREN 21 (2000).

²⁵⁴See *id.* at 28. On June 27, 2000, the British government announced that it intended to introduce legislation increasing the lump sum payment from £40,000 to £100,000, dropping the six-year statute of limitations, permitting anyone up to the age of 21 to ask for compensation, and reducing the severity of disability from 80 to 60 percent. *Id.* at 29.

²⁵⁵See Stephen D. Sugarman, *Beyond Compensation: Proposals for Reform*, 15 HAWAII L. REV. 659, 664-665 (1993).

Although there are many similarities among the different compensation programs, including their supplementary nature, the vaccines and injuries covered, the option for plaintiffs to pursue tort remedies, and the gaps in disability compensation under existing forms of social assistance making such programs necessary,²⁵⁶ the percentage of claims compensated and the total number of claims filed are difficult to compare. For example, the data shown below reflect a median percentage of 32.2 percent of claims compensated (New Zealand). The United States compensates roughly 30 percent of claims filed,²⁵⁷ and is therefore on par with other countries. However, “there is great variability across programs with respect to both the total number of claims filed and number of claims compensated. Accordingly, it is difficult to make valid comparisons in view of the significant differences in legislative language, the political and legal climate, and individual program longevity, process and decision-making. This is particularly true for the numbers of claims that are compensated.”²⁵⁸

In addition, the data also show that a smaller number of claims are filed in most other countries as compared with the United States. This may be due to broader social assistance programs provided by other countries that their respective populations regard as sufficient to cover most of their expenses.²⁵⁹ However, the total number of claims filed is also difficult to compare among the different programs, as it may depend on “population size, the numbers of vaccines administered, kinds of injuries covered, the willingness of the public to seek compensation under the governmental program versus other sources of compensation,” and

²⁵⁶ See Wendy K Mariner, *Compensation Programs for Vaccine-related Injury Abroad: A Comparative Analysis*, 31 ST. LOUIS U.L.J. 599, 633 (1987).

²⁵⁷ This statistic is a rough approximation of percentage of claims compensation, since it includes pre- and post-1988 cases, up to claims filed as of June 1999. See Geoffrey Evans, *Vaccine Injury Compensation Programs Worldwide*, VACCINE 17 S25, S26 (1999).

²⁵⁸ *Id.* at S29-S30.

²⁵⁹ See Wendy K Mariner, *Compensation Programs for Vaccine-related Injury Abroad: A Comparative Analysis*, 31 ST. LOUIS U.L.J. 599, 654 (1987).

public awareness of the program's existence.²⁶⁰

²⁶⁰Geoffrey Evans, *Vaccine Injury Compensation Programs Worldwide*, VACCINE 17 S25, S30 (1999).

Table 1: Vaccine injury compensation programs worldwide and percentage of claims awarded (as of June 1999)²⁶¹

Year Enacted	Germany	France	Japan	Denmark	New Zealand	Sweden	UK	Quebec	US	Taiwan	Italy
	1961	1964	1977 ²⁶²	1978 ²⁶³	1974	1978	1979	1985	1986	1988	1992
Number of Claims Compensated	1,139	37	2,720	5	68	79	890	17	1,390	62	260
Total Number of Claims Filed	4,569	51	2,982	55	211	140	4,012	142	5,355	123	366
Percentage of Claims Awarded	24.9	72.5	91.2	9.1	32.2	56.4	22.2	12.0	30.0	50.4	71.0

Although the numerical data are difficult to compare, the United States can still learn from and incorporate features of the other countries' compensation programs. Two especially unique programs, Sweden and New Zealand, are discussed in more detail below.

Sweden

²⁶¹See *id.* at S26.

²⁶²Japan initially set up a program in 1970 but implemented a more comprehensive program in 1977 that is currently in place. See *id.* at S27.

²⁶³Similarly, Denmark set up its program in 1972 but implemented its current program in 1978. See *id.*

The Swedish Pharmaceutical Insurance program greatly simplifies the claim process, requiring that the patient's physician, rather than attorney, help the patient's family file a claim. The claim and relevant medical records are then submitted to the insurer and reviewed initially by the insurer's medical assessor and then by physicians employed as advisors. They use a "preponderant probability" standard to determine causation, relying on a statistical causal relationship, where a chronological connection can be given substantial weight.²⁶⁴ Assessors also consider factors other than causation in determining compensation eligibility, including the nature and severity of the treated disease, general health of patient, severity of reaction, and foreseeability of the reaction. Any subsequent disputes are referred to the Drug Injury Committee, which then issues a statement on its findings whether or not the claim deserves compensation. If the family still disputes the committee's findings, arbitrators make final determinations in accordance with the Swedish Arbitration Act.²⁶⁵

To be compensated under Sweden's program, the plaintiff must be seriously disabled measured by bodily injury and/or time away from work.²⁶⁶ In 1986, maximum recovery was \$69,500 with an average indemnification of \$12,000.²⁶⁷ Although these awards may seem minimal by our standards (the overall pre-1988 injury award averages \$843,137),²⁶⁸ Sweden's program is only one of a diffuse network of medical insurance plans that already cover many of its citizens' medical expenses. One commentator observes that "70 percent of all benefits under the Swedish Pharmaceutical Insurance are used to compensate pain and suffering and that lost wages, medical treatment, and nursing care are covered by other national programs."²⁶⁹

²⁶⁴See Carl Oldertz, *Security Insurance, Patient Insurance, and Pharmaceutical Insurance in Sweden*, 34 AM. J. COMP. L. 635, 648 (1986).

²⁶⁵See Gregory C. Jackson, *Pharmaceutical Product Liability May be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U.L. REV. 199, 228 (1992).

²⁶⁶*Id.* at 229 n.196.

²⁶⁷*Id.* at 228.

²⁶⁸Heath Resources and Services Administration, Office of Special Programs, *National Vaccine Injury Compensation Program: Monthly Statistics Report* (Mar. 31, 2003), at <http://www.hrsa.gov/osp/vicp/monthly.htm>.

²⁶⁹Gregory C. Jackson, *Pharmaceutical Product Liability May be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U.L. REV. 199, 228 n.193 (1992).

This seems to reflect the primary goals of Sweden's program—compensation and spreading losses, wealth redistribution, and reduction of administrative costs. As Calabresi points out, “the basic deterrence/safety decision is achieved in Sweden through regulation, and the insurance plans work only to induce the extra or marginal safety that pain and suffering-type costs may make appropriate.”²⁷⁰ As a result, Sweden's compensation system results in decisions that take on “a measure of uniformity over time and provide both manufacturers and consumers with a degree of certainty of rights and responsibilities that is not possible at common law.”²⁷¹

New Zealand

New Zealand's legislature was strongly motivated by the inefficiencies of its own tort system when enacting its vaccine compensation program. The common law tort system cost about forty cents in transaction costs to deliver sixty cents in benefits.²⁷² This is in stark contrast to its compensation program, which costs about seven cents to deliver a dollar of benefits.²⁷³ Like Sweden, physicians help injured parties file claims which are then sent to the Accident Compensation Corporation Registration Centre (the “Corporation”). All medical claims, including vaccine injury claims, are forwarded to the Medical Misadventure, whose clinical advisors investigate the claims and secure medical and consultants' expert reports. An independent medical advisor then assesses the claim and makes his recommendations to the Medical Misadventure Advisory Committee (the “Committee”) who then makes its preliminary recommendation to the Corporation. The petitioner

²⁷⁰Guido Calabresi, *Policy Goals of the “Swedish Alternative,”* 34 AM. J. COMP. LAW 657, 665 (1986).

²⁷¹Gregory C. Jackson, *Pharmaceutical Product Liability May be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U.L. REV. 199, 229 (1992).

²⁷²See Sir Geoffrey Palmer, *The Ninth Monsanto Lecture: The Design of Compensation Systems: Tort Principles Rule, O.K.?* 29 VAL. U.L. REV. 1115, 1120 (1995).

²⁷³See *id.* at 1167.

and the Corporation have 15 days to comment on this recommendation; the Committee then gives its final advice to the Corporation.²⁷⁴ The petitioners may request an appeal by an independent Review Officer and then the District Court, but can only appeal to the High Court on matters of law only.²⁷⁵

Although examining the compensation programs from other countries may be instructive, what is efficient and effective depends on “what is likely to work within a given economy and political system.”²⁷⁶ Calabresi notes that within the United States, “any accident compensation fund that sought to tax injurer and victim activities according to their accident propensity would quickly be corrupted by political pressures.”²⁷⁷ However, the United States can adopt some of the other countries’ practices to streamline its own program, such as using a panel of neutral experts and considering factors other than scientific causation when assessing claims (as previously discussed), and having physicians, rather than attorneys, help patients file the initial claim to the PHS.

Implications for Other Areas of Medicine and the Law

One commentator argues that “there are probably very few other areas in which the government will have incentive to assume liability for harm caused by a manufactured product in order to prevent the manufacturers from ceasing production.”²⁷⁸ However, even though the entire program may not be completely transferable to other areas of tort litigation, components of the NVICP may nevertheless be helpful. Such innovations include the pre-trial status conference, using specialized decision makers to hear cases rather than lay juries, relaxing the rules of discovery and evidence, a statutory cap on damages, and the use of a table to define

²⁷⁴See MANITOBA LAW REFORM COMMISSION, COMPENSATION OF VACCINE-DAMAGED CHILDREN 31 (2000).

²⁷⁵*Id.* at 32.

²⁷⁶Guido Calabresi, *Policy Goals of the “Swedish Alternative,”* 34 AM. J. COMP. LAW 657, 659 (1986).

²⁷⁷*Id.* at 662.

²⁷⁸MOLLY TREADWAY JOHNSON, ET AL., FEDERAL JUDICIAL CENTER, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 53 (1998).

injures.

AIDS Vaccines

Because of the AIDS epidemic occurring worldwide, many patient advocates call for an expedited review process for an AIDS vaccine to not only encourage manufacturers to develop one, but also to prevent the infection of more potential AIDS victims. However, with an expedited review process and the devastating consequence of acquiring AIDS from an inoculation, vaccine manufacturers are understandably concerned about potential tort liability. California's AIDS Vaccine Program, very similar to the NVICP, would help alleviate some of those concerns (assuming that vaccine-related injuries can be well-defined) and hopefully facilitate and expedite the development of an effective and safe AIDS vaccine.²⁷⁹

Transfusion-Related HIV Infection

Another proposed area of compensation that the NVICP could serve as a model for is transfusion-related HIV infection, where the federal government would place a wholesale-level excise tax on all blood and blood products.²⁸⁰ However, this area is somewhat problematic to use an administrative no-fault compensation

²⁷⁹California had enacted a vaccine compensation program in 1977, similar to the NVICP, before the federal program was enacted, in its CAL. HEALTH AND SAFETY CODE § 429.35-36 (1977). In light of the NVICP's enactment, California officially repealed its compensation program in 1995. See Wendy K Mariner, *Compensation Programs for Vaccine-related Injury Abroad: A Comparative Analysis*, 31 ST. LOUIS U.L.J. 599 (1987).

²⁸⁰See Keith M. Garza, *Administrative No-Fault Recovery for Transfusion-Related HIV Infection*, 60 DEF. COUNS. J. 384 (1993).

scheme, since the nature of AIDS transmission raises serious issues of proving causation, including a long latency period and alternate modes of transmission through sexual intercourse and intravenous drug use.²⁸¹

Neurologically Impaired Infants

In 1987, a crisis of liability insurance availability and medical malpractice insurance affordability prompted the Virginia legislature to enact the Birth-Related Neurological Injury Compensation Act (the “Virginia Act”), which provides no-fault compensation for families whose infants suffered birth-related trauma resulting in serious neurological impairments, expressly excluding those caused by genetic or congenital defects.²⁸² This was seen as a preliminary step towards addressing the medical malpractice insurance crisis facing obstetricians and the medical profession in general. The program is primarily funded by physicians, hospitals, and non-participating physicians licensed to practice within the state of Virginia.²⁸³ If the fund becomes insolvent, then each insurance carrier is required to contribute an amount proportional to its share of total net premiums within Virginia to maintain the fund on an “actuarially sound basis.”²⁸⁴

The Virginia Act authorizes its Industrial Commission, responsible for adjudicating workers’ compensation claims, to determine compensation eligibility, with the aid of the Medical Advisory Panel, consisting of three physicians who file a report and recommendation of its findings of causation. Although the Commission is not bound by the Panel’s recommendations and makes the ultimate determination, it is more than likely

²⁸¹ *Id.*

²⁸² See David G. Duff, *Compensation for Neurologically Impaired Infants: Medical No-Fault in Virginia*, 27 HARV. J. ON LEGIS. 391 (1990).

²⁸³ Each participating physician is required to pay \$5,000 per year; each hospital is required to pay \$50 per delivery, not to exceed \$150,000 in a twelve-month period; and \$250 from each non-participating physician licensed to practice. The definition of “participating” physicians and hospitals is defined in the statute. See *id.* at 428.

²⁸⁴ *Id.* at 429.

that the Panel's findings will be accorded substantial weight.²⁸⁵ The plaintiff has the burden of proof to show that the infant suffered a spinal cord or brain injury caused by oxygen deprivation or mechanical injury from the delivery process, rendering the infant permanently non-ambulatory, aphasic, and incontinent.²⁸⁶ Some commentators have criticized the program as representing "a carefully crafted exercise in special interest legislation—promulgated in the interests of society as a whole, but conceived and orchestrated by a small segment of the medical community and the malpractice insurance industry."²⁸⁷ The Virginia Act adopts a specific deterrence approach, since the Commission refers all claims filed to the Board of Medicine and the Department of Health—administrative agencies that handle licensing and disciplinary matters for physicians and hospitals. However, this particular model of compensation may not be appropriate for medical negligence, since it reintroduces "a notion of moral responsibility into a scheme that presents itself as indifferent to fault."²⁸⁸

In addition to AIDS vaccines, transfusion-related HIV infections, and neurologically impaired infants injured during the delivery process, commentators have suggested the applicability of a compensation program similar to the NVICP to other areas of the law, including cases litigating products liability, mass torts, occupational exposure (including military exposure to chemical agents such as Agent Orange), breast implants, asbestos, and radiation.²⁸⁹ The commonality among many of these areas of the law is that aggregate injuries are alleged, the government accepts responsibility for liability, and the causal issues lend themselves to a narrow definition.²⁹⁰ Many critics of the current tort system hope that aspects of the NVICP can eventually realize their substantial potential in other areas of the law and improve the financial and emotional welfare of many more injured victims in the future.

²⁸⁵ *See id.*

²⁸⁶ *See id.* at 423-424.

²⁸⁷ *Id.* at 449.

²⁸⁸ *Id.* at 439 n.321.

²⁸⁹ *See* MOLLY TREADWAY JOHNSON, ET AL., FEDERAL JUDICIAL CENTER, USE OF EXPERT TESTIMONY, SPECIALIZED DECISION MAKERS, AND MANAGEMENT INNOVATIONS IN THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM 50 (1998).

²⁹⁰ *See id.*

Conclusion

“Until Americans have a comprehensive scheme of social insurance, courts must resolve by a balancing process the head-on collision between the need for adequate recovery and viable [business] enterprises.”²⁹¹ Congress attempted to help courts do this by doing its own cost-benefit analysis, weighing the immense benefits from a national vaccination program and the severe costs borne by a few who consequently suffer from serious adverse events, and enacted NVICP. “But for the families living with the emotional and economic strains of raising vaccine-injured children, or for those grieving the lost lives of young children with so much promise, the population-based cost-benefit analysis is hardly comforting.”²⁹² However, as one commentator stated: “It must be considered that there is nothing more difficult to carry out, nor more doubtful of success, nor more dangerous to handle, than to initiate a new order of things. For the reformer has enemies in all those who profit by the old order, and only lukewarm defenders in all those who profit by the new order.”²⁹³ Despite the criticisms and problems, the National Vaccine Injury Compensation Program is an innovative alternative to tort litigation and has enjoyed many successes in compensating vaccine-injured children in its short history. Although some critics argue that it is not that different from the tort system it aspired to replace, such as adversarial proceedings determining causation and long and uncertain adjudications, reforms proposed by this paper and the Improvement Act may help alleviate some of those problems. In addition, as the program itself matures, special masters gain more experience adjudicating claims, and the backlog of pre-1988 cases are slowly cleared, efficiency will improve, leading to more expedient resolutions of claims and more certain relief to injured parties. Although the NVICP cannot be applied to every area of tort and personal injury law, some of the program’s most salient and innovative features will serve as important

²⁹¹CLARK C. HAVIGHURST, JAMES F. BLUMSTEIN, AND TROYEN A. BRENNAN, HEALTH CARE LAW AND POLICY 1009 (1998).

²⁹²Elizabeth C. Scott, *the National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD DRUG L.J. 351, 353 (2001).

²⁹³Sir Geoffrey Palmer, *The Ninth Monsanto Lecture: The Design of Compensation Systems: Tort Principles Rule, O.K.?* 29 VAL. U.L. REV. 1115,1118 n.1 (1995), *quoting* Niccolo Machiavelli, *The Prince*, in *The Prince: And, the Discourses* 21 (1513).

models for many significant areas of tort reform.

Appendix A: Conflict and Bias Screening Questionnaire (for Potential Experts)²⁹⁴

In re:
SILICONE GEL BREAST IMPLANT
PRODUCTS LIABILITY LITIGATION

(MDL-926)

Silicone Breast Implant Science Panel
Potential Sources of Bias and Conflict of Interest Questionnaire

Instructions to Individuals Completing this Form

Before you start to complete the questionnaire please review the list of corporate defendants [omitted] and read the “General Statement Concerning Bias and Conflict of Interest” and “Instructions for Completing the Questionnaire.”

Do not skip any questions. If you require clarification of any of the items on the questionnaire, contact Professor Alan Wolf of the Selection Panel for assistance.

When you have completed the questionnaire, sign and date the form and return it to Professor Wolf by fax or express mail.

Promptly report to the Selection Panel any changes or additions to the information reported on this form while you are either being considered for service on the Science Panel or while serving on the Panel.

Contact Information

Name: (Mr./Mrs./Ms./Prof./Dr.) _____

Telephone: _____

Fax: _____

Email: _____

Title: _____

Employer: _____

Address: _____

²⁹⁴LAURAL L. HOOPER, JOE S. CECIL, THOMAS E. WILLING, FEDERAL JUDICIAL CENTER, NEUTRAL SCIENCE PANELS: TWO EXAMPLES OF PANELS OF COURT-APPOINTED EXPERTS IN THE BREAST IMPLANTS PRODUCTS LIABILITY LITIGATION 99-104 (2001).

General Statement Concerning Bias and Conflict of Interest

The Silicone Breast Implant Science Panel (hereafter, the “Science Panel”) will be charged with the responsibility of evaluating and critiquing pertinent scientific literature and studies bearing on issues of disease causation in the breast implant litigation. Since members of the Science Panel will be working directly for the court as neutral, independent experts, it is essential that panel members be free from any conflict of interest or significant bias as well as the appearance of such conflict or bias. This information is needed to ensure the integrity of the Science Panel. By screening potential members before they are selected, this questionnaire also safeguards panelists’ professional and personal reputations by minimizing the possibility that embarrassing conflict or bias issues will arise in the courtroom.

“Bias” generally refers to views stated or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the positions or perspectives of a particular group. For purposes of service on the Science Panel, the following are *examples* of potentially problematic forms of bias:

1. A panel member being placed in the position of reviewing his or her own work (or that of a family member, close friend, or colleague) for validity or scientific merit.
2. A panel member being committed to a fixed position on a particular issue through public statements (e.g., testimony, speeches, interviews, lectures, etc.), publication (e.g., articles, books, etc.), close identification or association with the positions or perspectives of a particular group, or through other personal or professional activities.

Certain forms of bias may be more properly characterized as conflicts of interest—e.g., where the individual is a senior officer of a professional society that espouses a fixed position on the issue.

“Conflict of Interest” means any financial or other interest which conflicts with the service of an individual because it could either impair the individual’s objectivity or create an unfair competitive advantage for any person or organization. A conflict is likely to be present where the efforts of the Science Panel may result in a direct or indirect economic benefit or loss to particular individuals or groups. Illustrative *examples* of direct economic benefit include:

1. A panel member (or member of his or her immediate household) has a significant financial investment or other close tie to a corporate defendant. (Highly diversified mutual funds investing in one or more corporate defendants do not constitute a significant investment.)
2. A panel member has a family member or close friend who is a party to the action, or who is otherwise involved in the litigation (e.g., a family member who is an attorney involved in the litigation).

Examples of indirect economic benefit include:

1. A panel member is a junior faculty member whose department chair (or other senior faculty) has taken a fixed position regarding the merits of this litigation.

2. For purposes of critically reviewing the relevant scientific literature, a panel member requests that another scientist furnish him or her with the raw data underlying a published work. Rather than using the data solely for the purposes of serving the court, the panel member envisions using the data for his or her own subsequent research efforts. (In such a case the panel member should contact all relevant parties for permission to use the data.)

The examples above are illustrative, but not all-inclusive. If you have any question as to the existence or appearance of bias or conflicts, please bring these matters to the attention of the Selection Panel.

Instructions for Completing the Questionnaire

Please note that the following questions refer variously to “you,” “you or any members of your household,” or, most broadly to “you, members of your household or members of your department.” Any reference to an “*interested party*” refers to:

- plaintiffs and defendants in the current litigation
 - individuals or organizations that are otherwise substantially involved in the current litigation (e.g., law firms)
- - individuals or organizations that otherwise have a stake in the outcome of the litigation (e.g., “educational” organizations funded primarily by a party or medical societies)
 - potential litigants (e.g., close friends or relatives who have implants, and are therefore potential plaintiffs).

Your responses to the following questions should be typed on additional sheets of paper, rather than on this form.

Please provide all relevant details for any questions answered in the affirmative. An affirmative response to one or more questions does not automatically disqualify you from serving on the panel. Further explanations may, however, be requested.

If the answer to a question is contained in your curriculum vitae you may simply refer to and attach the appropriate pages from it.

Personal interests

1. Are you or any members of your household interested parties?
2. Do you have close friends or family members who are plaintiffs in these actions, attorneys involved in this litigation, or are employed by defendant corporations?

Financial interests

3. Have you or members of your household ever worked for any interested party to the silicone breast implant litigation? (This includes both work relating to the implant litigation and any other type of work.)
4. Have you or members of your household ever received any research funds, graduate support, or any other funds (awards, honoraria, speaking or consulting fees, etc.) from any interested party?
5. Do you or members of your household currently have significant investments in any of the defendant corporations in the form of stocks, bonds, etc.? (You need not report highly diversified mutual funds or similar investment vehicles.) Do you or members of your household currently have investments in corporations which, although not parties to the litigation, have a stake in its outcome?
6. Have you, members of your household or members of your department conducted any research in the area of disease causation due to silicone breast implants? Was this research funded? If so, by whom? Did this research result in publication? If so, give citations.
7. Have you or members of your household conducted any research which was funded by corporations which, although not parties to the silicone implant litigation, have a stake in its outcome (e.g., pharmaceutical corporations that use silicone in medical devices)? Have you or members of your household served as consultants to such companies on any matter?

Public statement and positions

8. Have you, members of your household, or members of your department made any public pronouncements (e.g., to the press, to a class, or at a professional meeting) regarding: any aspect of the silicone breast implant litigation; the conduct of the parties to the litigation; your conclusions as to the relationship between breast implants and any of the medical conditions (e.g., systemic lupus, erythematosis, rheumatoid arthritis, scleroderma, polymyalgia) that plaintiffs complain of?
9. Do you have any colleagues²⁹⁵ at your institution or others, or a close friend at any institution, who has conducted research in the area of diseases allegedly caused by silicone breast implants? Have you ever shared a grant with these individuals? Have you ever co-authored any research publication with these individuals?
10. Have you or members of your household ever been contacted by anyone (e.g., parties, the press, lawyers) as regards silicone breast implants or the related litigation? What was the extent of this contact?

²⁹⁵“For purposes of this question a colleague is a person with whom you have a significant interaction in research, teaching or administration.” LAURAL L. HOOPER, JOE S. CECIL, THOMAS E. WILLGING, FEDERAL JUDICIAL CENTER, NEUTRAL SCIENCE PANELS: TWO EXAMPLES OF PANELS OF COURT-APPOINTED EXPERTS IN THE BREAST IMPLANTS PRODUCTS LIABILITY LITIGATION 103 (2001).

11. Have you ever reviewed a grant proposal or a journal article relating to diseases that might be caused by silicone breast implants?

Previous Litigation Experience

12. Have you ever served as an expert witness? If so, who were the parties to the action? For whom did you work? What was the nature of your involvement in that litigation? (e.g., did you prepare reports? testify? Were you deposed?)

Additional Information

13. Please report any service (full-time or part-time) with federal, state, or local government that may be related to the silicone breast implant litigation. Also include any other consulting or advisory work with professional organizations, trade associations, public interest groups, or civic groups that may be related to the litigation.

14. Is there any other connection between you and any interested party—or any other factor—that might impair your ability to serve on the Science Panel that has not been addressed by any of the above questions? Are there factors that others might reasonably construe as creating such impairments?

I have read the “General Statement Concerning Bias and Conflict of Interest” and the “Instructions for Completing the Questionnaire” and have answered the above questions in light of those statements, completely and to the best of my ability. I know of no reason why I cannot serve the Court as a neutral, unbiased, and independent expert.

SIGNATURE

DATE

Appendix B: Confidential Financial Disclosure Report for Special Government Employees (used by the FDA, updated in 2000)²⁹⁶

[REDACTED]

Appendix C: Conflict of Interest (“COI”) Criteria Guidance Table (merges Form FDA 3410 waiver criteria document and interim section 502 guidance)²⁹⁷

[REDACTED]

Appendix D: National Childhood Vaccine Injury Act Vaccine Injury Table and the Qualifications and Aids to Interpretation²⁹⁸

[REDACTED]

²⁹⁶United States Food and Drug Administration, Guidance on Conflicts of Interests for Advisory Committee Members, Consultants and Experts, *Confidential Financial Disclosure Report for Special Government Employees*, available at <http://www.fda.gov/oc/advisory/conflictinterest/disclosure.pdf> (Feb. 2000).

²⁹⁷United States Food and Drug Administration, Guidance on Conflicts of Interests for Advisory Committee Members, Consultants and Experts, *Conflict of Interest Criteria Guidance Table*, at <http://www.fda.gov/oc/advisory/conflictinterest/table.htm> (2000).

²⁹⁸Heath Resources and Services Administration, Office of Special Programs, *National Childhood Vaccine Injury Act Vaccine Injury Table and the Qualifications and Aids to Interpretation*, at <http://www.hrsa.gov/osp/vicp/table.htm>.